(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
9 December 2004 (09.12.2004)

PCT

(10) International Publication Number
WO 2004/105580 A2

(51) International Patent Classification[7]: A61B

(21) International Application Number: PCT/US2004/016004

(22) International Filing Date: 21 May 2004 (21.05.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

| | | |
|---|---|---|
| 60/472,817 | 22 May 2003 (22.05.2003) | US |
| 10/816,173 | 1 April 2004 (01.04.2004) | US |
| Not furnished | 20 May 2004 (20.05.2004) | US |

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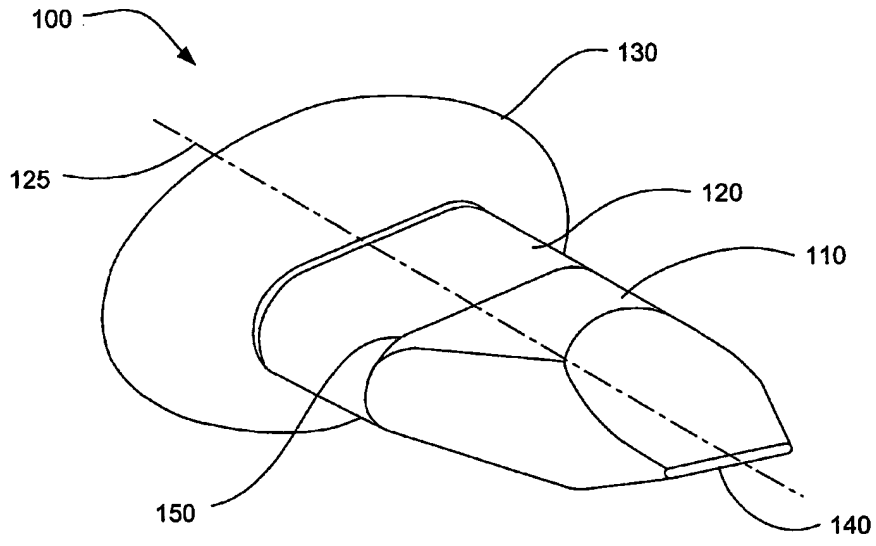
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH,

*[Continued on next page]*

(54) Title: DISTRACTIBLE INTERSPINOUS PROCESS IMPLANT AND METHOD OF IMPLANTATION




(57) Abstract: Systems and method in accordance with embodiment of the present invention can includes a distractible implant comprising a distracting insert and a body having a first part and a second part adapted to be positioned between adjacent spinous processes of cervical vertebrae. The distracting insert can be inserted into cavities of the body, thereby urging apart the first part and second part, and distracting the adjacent spinous processes.

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GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

**Published:**

— *without international search report and to be republished upon receipt of that report*

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

# DISTRACTIBLE INTERSPINOUS PROCESS IMPLANT AND METHOD OF IMPLANTATION

## CLAIM OF PRIORITY

**[0001]** This application claims priority to the following United States Patent Applications:

**[0002]** U.S. Provisional Patent Application No. 60/472,817, entitled "CERVICAL INTERSPINOUS PROCESS DISTRACTION IMPLANT AND METHOD OF IMPLANTATION," by James F. Zucherman, et al., filed May 22, 2003, which is incorporated herein by reference;

**[0003]** U.S. Patent Application No. 10/816,173, entitled "CERVICAL INTERSPINOUS PROCESS DISTRACTION IMPLANT AND METHOD OF IMPLANTATION," by James F. Zucherman, et al., filed April 1, 2004, which is incorporated herein by reference; and

**[0004]** U.S. Patent Application No. _____, entitled "DISTRACTIBLE INTERSPINOUS PROCESS IMPLANT AND METHOD OF IMPLANTATION," by James F. Zucherman, et al., filed May 20, 2004 (Attorney Docket No. KLYC-01087US2), which is incorporated herein by reference.

## TECHNICAL FIELD

**[0005]** This invention relates to interspinous process implants.

## BACKGROUND OF THE INVENTION

**[0006]** The spinal column is a bio-mechanical structure composed primarily of ligaments, muscles, vertebrae and intervertebral disks. The bio-mechanical functions of the spine include: (1) support of the body, which involves the transfer of the weight and the bending movements of the head, trunk and arms to the pelvis and legs, (2) complex physiological motion between these parts, and (3) protection of the spinal cord and the nerve roots.

**[0007]** As the present society ages, it is anticipated that there will be an increase in adverse spinal conditions which are characteristic of older people. By way of example only, with aging comes an increase in spinal stenosis (including, but not limited to, central canal and lateral stenosis), and facet arthropathy. Spinal stenosis results in a reduction foraminal area (*i.e.*, the available space for the passage of nerves and blood vessels) which

compresses the cervical nerve roots and causes radicular pain. Humpreys, S.C. *et al.*, *Flexion and traction effect on C5-C6 foraminal space*, Arch. Phys. Med. Rehabil., vol. 79 at 1105 (Sept. 1998). Another symptom of spinal stenosis is myelopathy, which results in neck pain and muscle weakness. *Id.* Extension and ipsilateral rotation of the neck further reduces the foraminal area and contributes to pain, nerve root compression and neural injury. *Id.*; Yoo, J.U. *et al.*, *Effect of cervical spine motion on the neuroforaminal dimensions of human cervical spine*, Spine, vol. 17 at 1131 (Nov. 10, 1992). In contrast, neck flexion increases the foraminal area. Humpreys, S.C. *et al.*, at 1105.

**[0008]** Pain associated with stenosis can be relieved by medication and/or surgery. It is desirable to eliminate the need for major surgery for all individuals, and in particular, for the elderly.

**[0009]** Accordingly, a need exists to develop spine implants that alleviate pain caused by spinal stenosis and other such conditions caused by damage to, or degeneration of, the cervical spine. Such implants would distract, or increase the space between, the vertebrae to increase the foraminal area and reduce pressure on the nerves and blood vessels of the cervical spine.

**[0010]** A further need exists for development of a minimally invasive surgical implantation method for cervical spine implants that preserves the physiology of the spine.

**[0011]** Further, a need exists for an implant that accommodates the distinct anatomical structures of the spine, minimizes further trauma to the spine, and obviates the need for invasive methods of surgical implantation. Additionally, a need exists to address adverse spinal conditions that are exacerbated by spinal extension.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0012]** **FIG. 1** is a perspective view of an embodiment of an implant in accordance with the present invention having a spacer, a distraction guide, and a wing with an elliptical cross-section.

**[0013]** **FIG. 2** is an end view of the implant of **FIG. 1**.

**[0014]** **FIG. 3** is a perspective view of another embodiment of an implant in accordance with the present invention having a wing with a teardrop-shaped cross-section.

**[0015]** **FIG. 4** is an end view of a second wing for use with the implant of **FIG. 3**.

**[0016]** **FIG. 5** is a perspective view of an embodiment of an implant in accordance with the present invention having a rotatable spacer and a wing with an elliptical cross-

section.

**[0017]** **FIG. 6** is a perspective view of an embodiment of an implant in accordance with the present invention having a rotatable spacer with two wings that are teardrop-shaped in cross-section.

**[0018]** **FIG. 7** depicts the axis of rotation of the implant of **FIG. 6** as seen from an end view.

**[0019]** **FIG. 8** is a perspective view of an embodiment of an implant in accordance with the present invention having a wing that is truncated at a posterior end.

**[0020]** **FIG. 9A** is an end view of an embodiment of an implant in accordance the present invention having a wing truncated at a posterior end and a rotatable spacer.

**[0021]** **FIG. 9B** is a truncated second wing for use with the implant of **FIG. 9A**.

**[0022]** **FIG. 10** is a plan view of an embodiment of an implant in accordance with the present invention wherein a screw is used to secure a second wing to the spacer.

**[0023]** **FIG. 11** is a perspective view of the second wing of **FIG. 10**.

**[0024]** **FIG. 12** is a perspective view of the implant of **FIG. 10**.

**[0025]** **FIG. 13A** is a front view of a second wing for use with some embodiments of implants of the present invention having a flexible hinge mechanism for securing the second wing to an implant.

**[0026]** **FIG. 13B** is a side-sectional view of the second wing of **FIG. 13A**.

**[0027]** **FIG. 14A** is a plan view of an embodiment of an implant for use with the second wing of **FIGs. 13A** and **13B**.

**[0028]** **FIG. 14B** is a front view of the second wing of **FIGs. 13A** and **13B**.

**[0029]** **FIG. 15A** is a top view of an embodiment of an implant in accordance with the present invention positioned between the spinous processes of adjacent cervical vertebrae.

**[0030]** **FIG. 15B** is a top view of the implant of **FIG. 15A**.

**[0031]** **FIG. 16** is a top view of two such implants of the invention as seen in **FIG. 15**, positioned in the cervical spine.

**[0032]** **FIG. 17** is a side view of two implants of the invention positioned in the cervical spine, with stops or keeps at the distal ends of the spinous processes.

**[0033]** **FIG. 18** is a perspective view of an alternative embodiment of an implant for use with systems and methods of the present invention.

[0034] **FIG. 19A** is an end view of an implant in accordance with still another embodiment of the present invention having a first part shaped to conform roughly with a contact surface of the spinous process.

[0035] **FIG. 19B** is a cross-sectional view of a spacer and a distracting insert in accordance with one embodiment of the present invention.

[0036] **FIG. 19C** is a cross-sectional view of a spacer and a distracting insert in accordance with an alternative embodiment of the present invention.

[0037] **FIG. 19D** is a cross-sectional view of a spacer and a distracting insert in accordance with still another embodiment of the present invention.

[0038] **FIG. 20A** is a front view of the implant of **FIG. 18** inserted between spinous processes.

[0039] **FIG. 20B** is a front view of the implant of **FIG. 20A** having a distracting insert positioned within cavities of the implant.

[0040] **FIG. 21A** is a cross-sectional side view of the implant of **FIG. 18** showing a distracting insert partially inserted in a cavity of the implant having pins for aligning a first portion with a second portion.

[0041] **FIG. 21B** is a top view of the implant of **FIG. 21A** showing positioning of pins for alignment of the first part and second part.

[0042] **FIG. 22A** is a perspective view of an alternative embodiment of an implant for use with systems and methods of the present invention, wherein the distracting insert includes a clip.

[0043] **FIG. 22B** is a side view of the implant of **FIG. 22A** showing a distracting insert mated with the implant.

[0044] **FIG. 22C** is a side view of an alternative embodiment of an implant mated with an alternative embodiment of a distracting insert.

[0045] **FIG. 22D** is a side view of still another embodiment of an implant mated with still another embodiment of a distracting insert.

[0046] **FIG. 23** is a perspective view of an embodiment of a distractible implant in accordance with the present invention having a second wing for limiting or blocking shifting along the longitudinal axis.

[0047] **FIG. 24** illustrates an embodiment of a method for implanting an interspinous implant in accordance with the present invention.

[0048] **FIG. 25** illustrates an alternative embodiment of a method for implanting an interspinous implant in accordance with the present invention.

## DETAILED DESCRIPTION

[0049] INTERSPINOUS IMPLANTS

[0050] **FIGs. 1** and **2** illustrate an implant **100** in accordance with an embodiment of the present invention. The implant **100** comprises a wing **130**, a spacer **120**, and a lead-in tissue expander (also referred to herein as a distraction guide) **110**. The distraction guide **110** in this particular embodiment is wedge-shaped, *i.e.*, the implant has an expanding cross-section from a proximal end of the implant **140** to a region **150** where the guide **110** joins with the spacer **120** (referencing for the figures is based on the point of insertion of the implant between spinous processes). As such, the distraction guide functions to initiate distraction of the soft tissue and the spinous processes when the implant **100** is surgically inserted between the spinous processes. It is to be understood that the distraction guide can be pointed and the like, in order to facilitate insertion of the implant between the spinous processes of adjacent cervical vertebrae. It is advantageous that the insertion technique disturb as little of the bone and surrounding tissue or ligaments as possible in order to reduce trauma to the site and promote early healing, and prevent destabilization of the normal anatomy. In the embodiment of **FIGs. 1** and **2**, there is no requirement to remove any of the bone of the spinous processes and no requirement to sever, or remove from the body, ligaments and tissues immediately associated with the spinous processes. For example, it is unnecessary to sever the *ligamentum nuchae,* (supraspinous ligament) which partially cushions the spinous processes of the upper cervical vertebrae.

[0051] As can be seen in **FIGs. 1-3**, the spacer **120** can be teardrop-shaped in cross-section perpendicular to a longitudinal axis **125** of the implant. In this way, the shape of the spacer **120** can roughly conform to a wedge-shaped space, or a portion of the space, between adjacent spinous processes within which the implant **100** is to be positioned. In other embodiments, the spacer **120**, can have alternative shapes such as circular, wedge, oval, ovoid, football-shaped, and rectangular-shaped with rounded corners and other shapes, and be within the spirit and scope of the invention. The shape of the spacer can be selected for a particular patient so that the physician can position the implant as close as possible to

the anterior portion of the surface of the spinous process. The shape selected for the spacer **120** can effect the contact surface area of the implant **100** and the spinous processes that are to be subject to distraction. Increasing the contact surface area between the implant and the spinous processes can distribute the force and load between the spinous frame and the implant.

**[0052]** As can be seen in **FIG. 2**, the wing **130** in this embodiment **100** is elliptically-shaped in cross-section perpendicular to a longitudinal axis **125** of the spacer **120** and distraction guide **110**. The dimensions of the wing **130** can be larger than that of the spacer **120**, particularly along the axis of the spine, and can limit or block lateral displacement of the implant in the direction of insertion along the longitudinal axis **125**. As illustrated in the embodiment of **FIG. 3**, the wing **130** can have other cross-sectional shapes, such as teardrop, wedge, circular, oval, ovoid, football-shaped, and rectangular-shaped with rounded corners and other shapes, and be within the spirit and scope of the invention. The wing **130** has an anterior portion **133** and a posterior portion **135**.

**[0053]** In other embodiments, the implant **100** can have two wings, with a second wing **160** (shown in **FIG. 4**) separate from the distraction guide **110**, spacer **120** and first wing **130**. The second wing can be connected to the proximal end of the spacer **120**. The second wing **160**, similar to the first wing **130**, can limit or block lateral displacement of the implant **100**, however displacement is limited or blocked in the direction opposite insertion. When both the first wing **130** and second wing **160** are connected with the implant and the implant is positioned between adjacent spinous processes, a portion of the spinous processes can be sandwiched between the first and second wing, limiting any displacement along the longitudinal axis **125**.

**[0054]** As can be seen in **FIG. 4**, the second wing **160** can be teardrop-shaped in cross-section. The wider section or end **162** of the teardrop shape is the posterior end of the second wing **160** and the narrower section or end **169** is the anterior end of the second wing **160**. Unlike the first wing **130**, however, the sides of the second wing **160** define a space **170** with a lip **180** that allows the second wing **160** to pass over the distraction guide **110** to meet and connect with the spacer **120**. The second wing **160** is then secured to the spacer **120** toward the end of the spacer located distally from the first wing **140**. The second wing **160** is connected with the implant after the implant **100** is positioned between the spinous processes.

[0055] It is to be understood that the implant can be made in two pieces. The first piece can include the first wing **130**, the spacer **120**, and the distraction guide **110**. The second piece can include the second wing **160**. Each piece can be manufactured using technique known in the art (e.g., machining, molding, extrusion). Each piece, as will be more fully discussed below, can be made of a material that is bio-compatible with the body of the patient. For example the implants can be made of stainless steel and titanium. Additionally, a shape memory metal such as Nitinol, which is a combination of titanium and nickel, can also be used. Further polymers can also be used. The implant can be formed with multiple pieces and with the pieces appropriately joined together, or alternatively, the implant can be formed as one piece or joined together as one piece.

[0056] Further embodiments of implants in accordance with the present invention are depicted in **FIGs. 5-7.** In such embodiments, the spacer **210** can be rotatable about the longitudinal axis **240** relative to the first wing **130**, or relative to a first and second wing **130,160** where two wings are used. The spacer **210** can be rotatable or fixed relative to the distraction guide **110**. Where the spacer **210** is rotatable, the spacer **210** can include a bore **220** running the length of the longitudinal axis **240**, and a shaft **230** inserted through the bore **220** and connecting the distraction guide **110** with the first wing **130**. It can be advantageous to position any of the implants taught herein as close as possible to the vertebral bodies. The rotatable spacer **210** can rotate to conform to or settle between the bone structures of the cervical spine as the implant is inserted between the spinous processes, so that on average the contact surface area between the spacer **210** and both of the spinous processes can be increased over the contact surface area between a fixed spacer **210** and the spinous processes. Thus, the rotatable spacer **210** improves the positioning of the spacer independent of the wings relative to the spinous processes. The embodiment of **FIG. 6** has a first wing **130** and if desired, a second wing **160** similar to the wing depicted in the embodiment of **FIG. 3**. As discussed below, the shape of the wings in **FIGs. 3** and **6** is such that the implants accommodate the twisting of the cervical spine along its axis as, for example, the head of a patient turning from side to side.

[0057] **FIG. 8** is a perspective view and **FIG. 9A** is an end view of still another embodiment of an implant in accordance with the present invention, wherein the posterior portion **135** of the teardrop-shaped first wing **130** is truncated **310**, making the first wing **130** more ovoid in shape. In this configuration, the anterior portion **133** of the first wing **130** can

be longer than the truncated posterior end **310** of the first wing **130**. As in previous embodiments, the spacer **210** of such implants **300** can be a rotatable spacer rather than a fixed spacer. **FIG. 9B** illustrates a second wing for use with such implant **300** having a truncated posterior end **340**. Truncation of the posterior ends **310,340** of the first and second wings **130,160** can reduce the possibility of interference of implants **300** having such first and second wings **130,160** positioned between spinous processes of adjacent pairs of cervical vertebrae, e.g., implants between cervical vertebrae five and six, and between six and seven. During rotation of the neck, the spinous process move past each other in a scissor-like motion. Each cervical vertebra can rotate relative to the next adjacent cervical vertebra in the general range of about 6°-12°. In addition, about 50 percent of the rotational movement of the neck is accomplished by the top two neck vertebrae. Thus, such embodiments can accommodate neck rotation without adjacent embodiments interfering with each other.

**[0058]** With respect to the prior embodiments which have first and second wings, the second wing **160**, can be designed to be interference-fit onto the spacer **120** (where the spacer is fixed) or a portion of the distraction guide **110** adjacent to the spacer **120** (where the spacer is rotatable). Where the second wing **160** is interference-fit, there is no additional attachment device to fasten the second wing **160** relative to the remainder of the implant. Alternatively, various fasteners can be used to secure the second wing **160** relative to the remainder of the implant. For example, **FIGs. 10-12** illustrate an embodiment of an implant **400** including a teardrop-shaped second wing **410** having a bore **420** through a tongue **430** at the posterior end of the second wing **160**. The bore on the second wing **420** is brought into alignment with a corresponding bore **440** on the spacer **120** when the second wing **160** is brought into position by surgical insertion relative to the rest of the implant. A threaded screw **450** can be inserted through the aligned bores in a posterior-anterior direction to secure the second wing **160** to the spacer **120**. The direction of insertion from a posterior to an anterior direction has the screw engaging the bores and the rest of the implant along a direction that is generally perpendicular to the longitudinal axis **125**. This orientation is most convenient when the surgeon is required to use a screw **450** to secure the second wing **160** to the rest of the implant. Other securing mechanisms using a member inserted into corresponding bores **420,440** on the spacer **120** and second wing **160** are within the spirit of the invention. It should be understood that a rotatable spacer **210** also can be accommodated by this embodiment. With a rotatable spacer **210**, the second wing **160** would be attached to a

portion of the distraction guide **110** that is located adjacent to the rotatable spacer **210**.

**[0059]** **FIGs. 13A-14B** depict a further embodiment **500** wherein the second wing **160** is secured to the spacer **120** by a mechanism including a flexible hinge **515**, with a protrusion **530** on the end of the hinge **510** adjacent to the lip **180** of the hole **170** defined by portions of the second wing **160**. The securing mechanism also encompasses an indentation **540** on the spacer **120**, wherein the indentation accommodates the protrusion **530** on the end of the flexible hinge **515**. During surgery, after insertion of the distraction guide **110**, spacer **120**, and first wing **130**, the second wing **160** is received over the distraction guide **110** and the spacer **120**. As the second wing **160** is received by the spacer **120**, the flexible hinge **515** and its protrusion **530** deflect until the protrusion **530** meets and joins with the indentation **540** in the spacer **120**, securing the second wing **160** to the spacer **120**. Again in embodiments where the spacer can rotate, the indentation **540** is located on an end of the distraction guide **110** that is adjacent to **150** the rotatable spacer **210**. With respect to the flexible hinge **515**, this hinge is in a preferred embodiment formed with the second wing **160** and designed in such a way that it can flex as the hinge **515** is urged over the distraction guide **110** and the spacer **120** and then allow the protrusion **530** to be deposited into the indentation **540**. Alternatively, it can be appreciated that the indentation **540** can exist in the second wing **160** and the flexible hinge **515** and the protrusion **530** can exist on the spacer **120** in order to mate the second wing **160** to the spacer **120**. Still alternatively, the flexible hinge **515** can be replaced with a flexible protrusion that can be flexed into engagement with the indentation **540** in the embodiment with the indentation **540** in the spacer **120** or in the embodiment with the indentation **540** in the second wing **160**.

**[0060]** **FIGs. 15A-16** illustrate an embodiment of an implant **600** wherein anterior ends of a first wing **130** and second wing **160** flare out at an angle away from the spacer **120** and away from each other. The cervical spinous processes are themselves wedge-shaped when seen from a top view. That the implant **600** can roughly conform with the wedge shape so that the implant **600** can be positioned as close as possible to the vertebral bodies of the spine where the load of the spine is carried. Thus the first **130** and the second wings **160** are positioned relative to the spacer, whether the spacer is fixed **120** or rotatable **210**, so that the wings flare out as the wings approach the vertebral body of the spine. **FIG. 15B** depicts a top view of the implant **600** of **FIG. 15A**. As is evident from **FIG. 15B**, the first wing **130** is aligned at an angle with respect to a line perpendicular to the longitudinal axis. In one embodiment,

the angle is about 30°, however, the angle $\theta$ can range from about 15° to about 45°. In other embodiments, other angles of the first wing **130** relative to the spacer **120** outside of this range are contemplated and in accordance with the invention. Likewise, the second wing **160** can be aligned along a similar, but oppositely varying range of angles relative to the line perpendicular to the longitudinal axis. The first and second wing **130,160** thus form an obtuse angle with respect to the spacer **120** in this embodiment. The second wing **160** defines an inner hole **170** which is outlined by the lip **180**. As is evident, the lip **180** can be provided at an angle relative to the rest of the second wing **160** so that when the lip **180** is urged into contact with the spacer **120**, the second wing **160** has the desired angle relative to the spacer **120**. As discussed above, there are various ways that the second wing **160** is secured to the spacer **120**. **FIG. 15A** depicts a top view of one such implant **600** placed between the spinous processes of adjacent cervical vertebrae. **FIG. 16** is a top view illustrating two layers of distracting implants **600** with flared wings.

**[0061]** Systems and methods in accordance with the present invention can include devices that can be used in cooperation with implants of the present invention. **FIG. 17** illustrates "stops" (also referred to herein as "keeps") **710**, which are rings of flexible biocompatible material, which can be positioned around the spinous processes of adjacent cervical vertebrae and located posteriorly to the implant. The keeps **710** can prevent posterior displacement of the implants. In one embodiment, the keeps can include a ring **710** having a slit **720**. The keeps **710** can be somewhat sprung apart, so that the keep **710** can be fit over the end of the spinous process and then allowed to spring back together in order to hold a position on the spinous process. The keep **710** can act as a block to the spacer **120** in order to prevent the implant from movement in a posterior direction.

**[0062]** DISTRACTIBLE INTERSPINOUS IMPLANTS

**[0063]** In still other embodiments, implants in accordance with the present invention can be distractible *in situ*. **FIG. 18** is a perspective view of one such implant. The implant **1800** comprises a body **1801** adapted to be inserted between the spinous processes, and a distracting insert **1806**. The body **1801** can include two substantially mirror parts: a first part **1802** adapted to contact and support an upper spinous process and a second part **1804** adapted to contact and support a lower spinous process. When positioned such that the first and second parts **1802,1804** align with and abut one another, the body **1801** can resemble

implants described above in reference to **FIGs. 1-17**. In other embodiments, the body **1801** can have a shape other than those shown in **FIGs. 1-17**. Further, in some embodiments the first part **1802** and second part **1804** can have different shapes, such that when the first part **1802** and second part **1804** align with and abut one another, the body **1801** is nonsymmetrical about the plane of contact. For example, as shown in **FIG. 19A**, the first part **1802** can have a saddle-like, or concave shape conforming roughly with a shape of a contact surface of the second cervical, while the second part **1804** has a substantially convex shape.

**[0064]** The body **1801** can include a wing **1830** having a first and second portion **1832,1834**, a spacer **1820** having a first and second portion **1822,1824**, and a lead-in tissue expander (also referred to herein as a distraction guide) **1810** having a first and second portion **1812,1814**. The distraction guide **1810** as shown is wedge-shaped, *i.e.*, the distraction guide **1810** has an expanding cross-section from the proximal end of the body **1801** to a region where the distraction guide **1810** joins with the spacer **1820**. As such, the distraction guide **1810** functions to initiate distraction of the soft tissue and the spinous processes when the body **1801** is surgically inserted between the spinous processes.

**[0065]** The spacer **1820**, as shown, is teardrop-shaped in a cross-section perpendicular to the spacer's longitudinal axis **1825**. The spacer **1820** can be shaped to roughly conform to a wedge-like space, or a portion of the space, between adjacent spinous processes, for example as between the spinous processes of the fourth and fifth cervical vertebrae. The shape of the spacer **1820** can be selected for a particular patient, and/or a particular pair of adjacent spinous processes, and can vary substantially. Thus, in other embodiments, the spacer **1820** can have other cross-sectional shapes, such as circular, wedge, oval, ovoid, football-shaped, and rectangular-shaped with rounded corners and other cross-sectional shapes and/or can be custom fabricated for the particular patient and the anatomy of the particular spinal processes between which the implant **1800** is to be placed. In still other embodiments, the spacer **1820** can have a nonsymmetrical cross-sectional shape, for example where a space between adjacent spinous processes is nonsymmetrical. The ability to select a size and shape of the spacer **1820** to suit a patient allows the physician to choose an implant **1800** that can be placed closer to the vertebral bodies than farther away for additional support. The shape selected for the spacer **1820** can define the contact surface area between the implant **1800** and the spinous processes that are subject to distraction. Increasing the contact surface area between the implant **1800** and the spinous processes

distributes the force and load between the spinous frame and the implant **1800**. Generally, a teardrop or wedge-shaped spacer **1820** can allow for more load-bearing contact between the spacer **1820** and the spinous processes of the cervical vertebrae, and embodiments having such shapes will be more particularly described.

**[0066]** As shown, the wing **1830** can be tear-drop shaped in cross-section, although having a minor dimension that is larger than that of the spacer **1820**, and can limit or block lateral displacement of the implant **1800** in the direction of insertion along the longitudinal axis **1825**. However, the wing **1830** need not be teardrop shaped. In other embodiments, the wing **1830** can have some other shape, for example the wing **1830** can be elliptical, wedge, circular, oval, ovoid, football-shaped, and rectangular-shaped with rounded corners and other shapes, and be within the spirit and scope of the invention. Further, as with the spacer **1820**, the wing **1830** can have a nonsymmetrical cross-sectional shape. The shape of the wing **1830** can be chosen to most easily fit into place while avoiding obstructions, such as soft tissue or bone, or other implants, while still blocking or limiting lateral displacement.

**[0067]** The wing **1830** can include one or more cavities **1852,1854** that extend through the wing **1830** and through at least a portion of the spacer **1820**. The one or more cavities **1852,1854** should comprise a first groove formed in the first part **1802** and a second groove formed in the second part **1804**, so that the cross-section of the cavity **1852,1854** can be expanded during insertion of a distracting insert **1806**, as described below. The body **1801** of **FIG. 18** includes a first cavity **1852** and a second cavity **1854** to receive a first insert **1842** and a second insert **1844** of the distracting insert **1806**. Having two or more cavities and corresponding inserts can prevent relative rotation between the body **1801** and the distracting insert **1806**. In the embodiment shown in cross-section in **FIG. 19B**, each cavity has a substantially circular cross-section, and is sized roughly in proportion to the width of the spacer **1820**, so that the first cavity **1852** is larger in diameter than the second cavity **1854**. However, in other embodiments, the cavities need not be shaped as shown. For example, the cavities can be elliptical, dual-lobed, or otherwise shaped. Further, the cavities need not be sized as shown. For example, the cavities can be roughly the same size. As shown in **FIG. 19C**, in still further embodiments, the body **1801** can include more than two cavities **1852,1854,1856**, and each cavity can have similar, or different shape. As shown in **FIG. 19D**, in still other embodiments the body **1801** can include a single cavity **1852**, such as a wedge-shaped cavity roughly corresponding to a shape of the spacer **1820**. Myriad different cavity

shapes and cavity configurations can be employed to achieve separation of a body **1801** positioned between spinous processes. However, it can be preferable that the shape of the cavities **1852,1854,1856** should correspond roughly with the shape of the upper and lower surfaces of the inserts **1842,1844,1846** of the distracting insert **1806**, so that, as shown in **FIG. 19B-19D**, a load applied to the body **1801** can be distributed relatively evenly over the surface of the cavities **1852,1854,1856**.

**[0068]** Once the body **1801** is positioned between adjacent spinous processes, the first and second parts **1802,1804** of the body **1801** can be separated, thereby expanding the width of the body **1801** and distracting the adjacent spinous processes. In one embodiment, separation of the first and second parts **1802,1804** can be accomplished, for example, by positioning the distracting insert **806** within the body **1801** such that the first and second parts **1802,1804** are urged apart. As mentioned above, the distracting insert **1806** can include one or more inserts associated with the one or more cavities, the one or more inserts being fixedly connected to a cap **1808**. As shown in **FIG. 18**, the distracting insert **1806** includes a first insert **1842** and a second insert **1844**, each of the inserts being fixedly connected with a cap **1808** having a shape roughly corresponding to a shape of the wing **1830**. Inserts **1842, 1844** have distracting tips that can initially urge the halves of the implant **1800** apart. In other words, the inserts **1842,1844** have tips with ever-increasing cross-section so that the tips can be easily inserted in the cavities **1852,1854** and the continual movement of the insert **1842,1844** urges the halves of the body **1801** apart. Thus, the tips of the insert **1842,1844** can be smaller than the cavities **1852,1854** in order to facilitate initial insertion into the cavities **1852,1854**. As shown in **FIG. 19B-D**, the one or more inserts **1842,1844,1846** can be sized such that they have a height larger than a diameter (or height) of the one or more cavities **1852,1854,1856**, so that when positioning the inserts within the cavities, the first part **1802** and second part **1804** of the body **1801** are separated by the difference in height of the inserts and the diameter (or height) of the cavities – i.e., an additional distraction height.

**[0069]** As shown in **FIG. 20A**, the body **1801** can be inserted between adjacent spinous processes by piercing and/or displacing the soft tissue (i.e., the interspinous ligament) with the distraction guide **1810** and stretching and/or displacing the tissue so that the spacer **1820** fits between the spinous processes. The height of the first part **1802** and second part **1804** of the body **1801** can be minimized by abutting the first part **1802** and the second part **1804** so that the body **1801** can be positioned between the spinous processes.

As described above, and as can be seen in **FIG. 20A**, the shape of the body **1801** can resemble the shape of a space between adjacent spinous processes. With the body **1801** in place, the distracting insert **1806** can be inserted into the body **1801**, causing the first part **1802** and second part **1804** to separate, as described above and shown in **FIG. 20B**. As discussed above, proximal ends of the inserts **1842,1844** of the distracting insert **1806** can be tapered to assist in guiding the inserts **1842,1844** into the cavities **1852,1854**, and to ease separation of the first and second parts **1802,1804**. The distracting insert **1806** can have inserts **1842,1844** sized to achieve a desired amount of distraction of the spinous processes.

**[0070]** As with the body **1801**, multiple distracting inserts **1806** can be made available to a physician, the physician choosing a distracting insert **1806** sized to suit a particular patient. A system in accordance with one embodiment of the present invention can comprise a plurality of bodies **1801**, each body **1801** having different shape and/or height. Such a system can further comprise a plurality of distracting inserts **1806**, having inserts corresponding to cavities of the bodies **1801**, and having different heights to achieve different amounts of distraction. Methods in accordance with embodiments of the present invention can apply such systems so that a physician can select implant components appropriate to the patient at the time of surgery, and can further substitute different bodies and/or different distracting inserts based on evaluation or reevaluation during surgery.

**[0071]** **FIG. 21A** is a cross-sectional side view of a distractible implant **1800** in accordance with one embodiment of the present invention positioned between adjacent spinous processes, and having an insert **1842** of the distracting insert **1806** partially inserted within a cavity **1852** of the body **1801**. As described above, when inserted between spinous processes, the first part **1802** of the body **1801** is aligned and abutted with the second part **1804** of the body **1801**. The first part **1802** and second part **1804** should remain aligned while the body **1801** is inserted between the spinous processes, and further should remain aligned while the distracting insert **1806** is mated with the body **1801**. In order to maintain proper alignment, one of the first and second parts **1802,1804** can include alignment pins (or protrusions) **2118** that mate with corresponding holes **2119** of the other of the first and second parts **1802,1804**. The pins **2118** can be made of the same or different material as the body **1801**, and can be integrally formed or mated with the corresponding part. For example, where the pins **2118** are made of titanium, and the body **1801** is made of a biocompatible thermoplastic, the pins **2118** can be press fit into the second part **1804**. The pins **2118** are

free to slide in and out of the holes **2119**, but are prevented from separating from the holes **2119** by pressure of the spinous processes. As an insert **1842** enters a cavity **1852** of the body **1801**, the distal end of the body **1801** begins to separate, as shown. As the spinous processes are distracted, the pins **2118** move within the holes **2119**, allowing separation of the first part **1802** and second part **1804**. The pins **2118** prevent relative shifting or sliding along the longitudinal axis or along the length of the spinous process. The pins **2118** (and corresponding holes **2119**) preferably have a height larger than the maximum distraction height, thereby preventing the pins **2118** from separating from the holes **2119** and allowing relative shifting of the first and second parts **1802,1804**. **FIG. 21B** is a top view showing the position of the pins **2118** relative to a first and second cavity **1852,1854**. Two pins **2118** are shown extending through holes **2119** of the second part **1802**, however, in other embodiments, any number of pins **2118** or protrusions can be integrally formed or connected with one of the first and second parts **1802,1804**.

**[0072]** In an alternative embodiment (not shown), the first part **1802** and second part **1804** of the body **1801** can be bound together by a flexible, artificial ligament or suture material. For example, the material can be a bio-compatible polymer having flexible properties. The artificial ligament or suture material can limit the shifting between the first part **1802** and second part **1804**. In still other embodiments, some other device can be employed to maintain alignment of the first and second parts **1802,1804**. It is intended that in some embodiments of the present invention, it is preferable to maintain alignment of the first and second parts **1802,1804** during distraction. As one of ordinary skill in the art can appreciate, many different devices can be employed to maintain alignment between the first and second parts **1802,1804** of the body **1801**.

**[0073]** As shown in **FIGs. 22A** and **22B**, the distracting insert **1806** can be secured to the body **1801** by a clip **2260**. The body **1801** as shown in **FIGs. 22A-22D** is the same as the body **1801** of **FIG. 18**. Commonly labeled components are as described above. However, it should be noted that other embodiments of a body **1801** can be used with distracting inserts **1806** described with reference to **FIG. 22A-22D**. In one embodiment, the clip **2260** can include a first tab **2262** and a second tab **2264**. Each tab **2262,2264** can extend across at least a portion of the width of the respective portion of the wing **1830** along the longitudinal axis **1825**. When the distracting insert **1806** is mated with the body **1801**, the wing **1830** can be interference-fit with the distracting insert **1806** so that the wing **1830** is held between the

tabs **2262,2264**. The pressure applied to the surfaces of the wing **1830** should create sufficient frictional force to prevent relative movement between the body **1801** and distracting insert **1806**. In other embodiments, the clip **2260** can comprise a single lip along a portion of, or the entire periphery of the cap (and wing **1830**) and can extend across at least a portion of the width of the wing **1830** along the longitudinal axis **1825**.

**[0074]** As shown in **FIG. 22C**, in still other embodiments, each tab **2262,2264** can include a protrusion **2263,2265** located at a proximal end of the tab **2262,2264**. The wing **1830** can include indentations **2273,2275**, or cavities, for receiving each of the protrusions **2263,2265** so that when the protrusions are positioned within the respective indentations, the clip **2260** is locked in place. Alternatively, the tab **2262,2264** can extend beyond a ledged wing **1830**, so that the clip **2260** can be locked in place when the protrusions **2263,2265** clear the wing **1830**. As described above, the distracting insert **1806** is mated with the positioned body **1801** by gradually urging the inserts of the distracting insert **1806** along the length of the cavities of the spacer **1820**. The protrusions **2263,2265** can be beveled, so that as the protrusions contact an outer lip of the wing **1830**, the tabs **2262,2264** deflect upward, allowing the distracting insert **1806** to continue moving into position along the longitudinal axis. When the protrusions **2263,2265** find the indentations **2273,2275** of the wing **1830** (or alternatively, when the protrusions clear the ledge), the clasp **2260** locks into place and the distracting insert **1806** is mated with the body **1801**.

**[0075]** In still further embodiments, the distracting insert **1806** need not include a clip, but can be mated with the body **1801** using some other device. For example, as shown in **FIG. 22D**, an insert **1842** can include one or more pegs **2272,2274**, and one or more corresponding through-holes **2282,2284** (or cavities) within the first wing **1830**. The one or more pegs **2272,2274** can be sized such that a feature of the one or more pegs **2272,2274** is approximately the same width, or slightly larger than a width, **w**, of the one or more corresponding through-holes **2282,2284**, so that an interference fit is created between the distracting insert **1806** and the body **1801**, holding the distracting insert **1806** seated in place, and limiting the relative movement of the first part **1802** and second part **1804**.

**[0076]** Referring to **FIG. 23**, the implant **1800** can further include a second wing **2360**, similar to previously described embodiments. The second wing **2360** can be connected to the proximal end of the spacer **1820** so that portions of the adjacent spinous processes are sandwiched between the second wing **2360** and the first wing **1830**. The second wing **2360**,

like the first wing **1830**, can prevent lateral displacement of the body **1801** relative to the spinous processes. The second wing **2360** can be teardrop-shaped and sized to approximate the shape and size of the first wing **1830** when the distracting insert **1806** is mated with the body **1801**. Likewise, the sides of the second wing **2360** define a space **2370** with a lip **2380** that allows the second wing **2360** to pass over the distraction guide **1810** to meet and connect with the spacer **1820**. The space **2370** defined within the second wing **2360** should correspond with the distracted height of the body **1801**. As described above, systems and methods in accordance with the present invention can comprise a plurality of bodies **1801** and a plurality of distracting inserts **1806** to suit a particular patient. Likewise, systems and methods in accordance with the present invention can further comprise a plurality of second wings **2360** corresponding in size and shape to the plurality of bodies **1801** and the plurality of distracting inserts **1806**. The second wing **2360** can be secured to the spacer **1820**, for example as described above. The second wing **2360** is implanted once the distraction guide **1810**, spacer **1820**, and first wing **1830** are inserted as a unit between the spinous processes of adjacent cervical vertebrae.

**[0077]** It is to be understood that the various features of the various embodiments can be combined with other embodiments of the invention and be within the spirit and scope of the invention. Thus, for example only, the embodiment of **FIG. 18** can have truncated wings as depicted in other embodiments.

**[0078]** MATERIALS FOR USE IN IMPLANTS OF THE PRESENT INVENTION

**[0079]** It is to be understood that implants in accordance with the present invention, and/or portions thereof can be fabricated from somewhat flexible and/or deflectable material. In these embodiments, the implant and/or portions thereof can be made out of a polymer, such as a thermoplastic. For example, in one embodiment, the implant can be made from polyketone, known as polyetheretherketone (PEEK). Still more specifically, the implant can be made from PEEK 450G, which is an unfilled PEEK approved for medical implantation available from Victrex of Lancashire, Great Britain. Other sources of this material include Gharda located in Panoli, India. PEEK has the following approximate properties:

| Property | Value |
|---|---|
| Density | 1.3 g/cc |
| Rockwell M | 99 |
| Rockwell R | 126 |
| Tensile Strength | 97 MPa |
| Modulus of Elasticity | 3.5 GPa |
| Flexural Modulus | 4.1 GPa |

The material specified has appropriate physical and mechanical properties and is suitable for carrying and spreading a physical load between the adjacent spinous processes. The implant and/or portions thereof can be formed by extrusion, injection, compression molding and/or machining techniques.

**[0080]** In some embodiments, the implant can comprise, at least in part, titanium or stainless steel, or other suitable implant material which is radiopaque, and at least in part a radiolucent material that does not show up under x-ray or other type of imaging. For example, in one embodiment, a first wing, a second wing and a shaft can comprise a radiopaque material (e.g., titanium) and a rotatable spacer and a lead-in tissue expander can comprise a radiolucent material (e.g., PEEK). In such an embodiment, under imaging the implant looks like an "H". The physician can have a less obstructed view of the spine under imaging, than with an implant comprising radiopaque materials entirely. However, the implant need not comprise any radiolucent materials.

**[0081]** It should be noted that the material selected can also be filled. For example, other grades of PEEK are also available and contemplated, such as 30% glass-filled or 30% carbon-filled, provided such materials are cleared for use in implantable devices by the FDA, or other regulatory body. Glass-filled PEEK reduces the expansion rate and increases the flexural modulus of PEEK relative to that which is unfilled. The resulting product is known to be ideal for improved strength, stiffness, or stability. Carbon-filled PEEK is known to enhance the compressive strength and stiffness of PEEK and lower its expansion rate. Carbon-filled PEEK offers wear resistance and load carrying capability.

**[0082]** In this embodiment, as described above, the implant is manufactured from PEEK, available from Victrex. As will be appreciated, other suitable similarly biocompatible thermoplastic or thermoplastic polycondensate materials that resist fatigue, have good memory, are flexible, and/or deflectable, have very low moisture absorption, and good wear

and/or abrasion resistance, can be used without departing from the scope of the invention. The spacer can also be comprised of polyetherketoneketone (PEKK). Other material that can be used include polyetherketone (PEK), polyetherketoneetherketoneketone (PEKEKK), and polyetheretherketoneketone (PEEKK), and generally a polyaryletheretherketone. Further, other polyketones can be used as well as other thermoplastics. Reference to appropriate polymers that can be used in the implant can be made to the following documents, all of which are incorporated herein by reference. These documents include: PCT Publication WO 02/02158 A1, dated January 10, 2002, entitled "Bio-Compatible Polymeric Materials;" PCT Publication WO 02/00275 A1, dated January 3, 2002, entitled "Bio-Compatible Polymeric Materials;" and, PCT Publication WO 02/00270 A1, dated January 3, 2002, entitled "Bio-Compatible Polymeric Materials." Other materials such as Bionate®, polycarbonate urethane, available from the Polymer Technology Group, Berkeley, California, may also be appropriate because of the good oxidative stability, biocompatibility, mechanical strength and abrasion resistance. Other thermoplastic materials and other high molecular weight polymers can be used.

**[0083]** METHODS FOR IMPLANTING INTERSPINOUS IMPLANTS

**[0084]** A minimally invasive surgical method for implanting an implant **100,1800** in the cervical spine is disclosed and taught herein. In this method, as shown in **FIG. 24**, preferably a guide wire **2480** is inserted through a placement network **2490** into the neck of the implant recipient. The guide wire **2480** is used to locate where the implant is to be placed relative to the cervical spine, including the spinous processes. Once the guide wire **2480** is positioned with the aid of imaging techniques, an incision is made on the side of the neck so that an implant In accordance with an embodiment of the present invention, can be positioned in the neck thorough an incision and along a line that is about perpendicular to the guide wire **2480** and directed at the end of the guide wire **2480**. In one embodiment, the implant can be a sized implant **100** (i.e., having a body that is not distractable), such as described above in **FIGs. 1-17** and including a distraction guide **110**, a spacer **120**, and a first wing **130**. The implant **100** is inserted into the neck of the patient. Preferably during insertion, the distraction end pierces or separates the tissue without severing the tissue.

**[0085]** Once the implant **100** is satisfactorily positioned, a second wing **160** can be optionally inserted along a line that is generally colinear with the line over which the implant

100 is inserted but from the opposite side of the neck. The anatomy of the neck is such that it is most convenient and minimally invasive to enter the neck from the side with respect to the implant 100 and the second wing 160. The second wing 160 is mated to the implant and in this particular embodiment, the second wing 160 is snapped into engagement with the implant 100. In an alternative embodiment, the second wing 160 is attached to the implant by the use of a fastener, for example by a screw 450. Where a screw is used, the screw 450 can be positioned using a screw driving mechanism that is directed along a posterior to anterior line somewhat parallel to the guide wire 2480. This posterior to anterior line aids the physician in viewing and securing the second wing 160 to the implant.

[0086] In other embodiments of methods in accordance with the present invention, the implant can be a distractible implant 1800, such as described above in FIGs. 18-23. In such embodiments, as shown in FIG. 25, preferably a guide wire 2580 is inserted through a placement network 2590 into the neck of the implant recipient (as shown and described above). Once the guide wire 2580 is positioned with the aid of imaging techniques, an incision is made on the side of the neck so that a distractible body 1801 in accordance with an embodiment of the present invention, can be positioned in the neck thorough an incision and along a line that is about perpendicular to the guide wire 880 and directed at the end of the guide wire. The distractible body 1801 can include a distraction guide 1810, a spacer 1820, and a first wing 1830. The body 1801 is inserted into the neck of the patient, between adjacent spinous processes. Preferably during insertion, the distraction guide 1810 pierces or separates the tissue without severing the tissue, and the body 1801 is positioned so that the spacer 1820 is between the adjacent spinous processes. A distracting insert 1806 is then positioned within the incision and urged into one or more cavities of the body 1801, distracting the spinous processes between which the body is positioned. As the distracting insert 1806 mates with the body 1801, the distracting insert 1806 locks in place.

[0087] Once the distractible implant 1800 is satisfactorily positioned and distracted, a second wing 2360 can optionally be inserted along a line that is generally colinear with the line over which the body 1801 is inserted but from the opposite side of the neck. The anatomy of the neck is such that it is most convenient and minimally invasive to enter the neck from the side with respect to the body 1801 and the second wing 2360. The second wing 2360 can be mated to the body 1801 through an interference fit, or alternatively by attaching to the body 1801 by the use of a fastener, or by some other device, as described

above. For example, where a screw is employed, the screw can be positioned using a screw driving mechanism that is directed along a posterior to anterior line somewhat parallel to the guide wire. This posterior to anterior line aids the physician in viewing and securing the second wing **2360** to the body **1801**.

**[0088]** The foregoing description of the present invention have been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Many modifications and variations will be apparent to practitioners skilled in this art. The embodiments were chosen and described in order to best explain the principles of the invention and its practical application, thereby enabling others skilled in the art to understand the invention for various embodiments and with various modifications as are suited to the particular use contemplated. It is intended that the scope of the invention be defined by the following claims and their equivalents.

CLAIMS

What is claimed:

1. A device for relieving pain associated with the vertebrae of the cervical spine and surrounding tissues and structures, by maintaining and/or adding distraction between adjacent cervical vertebrae when positioned between the spinous processes of adjacent cervical vertebrae, without detracting from the rotation of the cervical vertebrae relative to each other, the implant comprising:

a. a wedge-shaped spacer;

b. a wedge-shaped wing; and

c. a wedge-shaped distraction guide.

2. The implant of claim 1 wherein the spacer has smooth, flat surfaces and smooth, rounded edges to create a wedge for varying distraction of adjacent cervical vertebrae.

3. The implant of claim 1 wherein the cross-sectional shape of the wing has smooth, flat surfaces and smooth, rounded edges to create a wedge for varying distraction of adjacent cervical vertebrae.

4. The implant of claim 1 wherein the wing is continuous with the spacer.

5. The implant of claim 1 wherein the distraction guide is continuous with the spacer.

6. The implant of claim 1 wherein the spacer is rotatable.

7. The implant of claim 1 including a second wing.

8. The implant of claim 1 wherein the spacer can rotate relative to the wing and the distraction guide.

9. The implant of claim 1 wherein the first wing is provided at an obtuse angle to the spacer

10. The implant of claim 1 wherein the first wing has a posterior end and an anterior end, and the posterior end does not extend as far beyond the posterior end of the spacer as the anterior end extends anteriorly to the anterior end of the spacer.

11. A device for relieving pain associated with the vertebrae of the cervical spine and surrounding tissues and structures, by maintaining and/or adding distraction between adjacent cervical vertebrae when positioned between the spinous processes of adjacent cervical vertebrae, without detracting from the rotation of the cervical vertebrae relative to each other, the implant comprising:

a. a wedge-shaped distraction guide;

b. a wedge-shaped spacer associated with the wedge-shaped distraction guide, which spacer, when urged between the spinous process of the adjacent cervical vertebrae, allows flexion but not extension of the neck and creates a contact surface with the bone of the spinous processes that increases as the wedge-like spacer moves anteriorly, whereby the implant distributes the distraction forces on the spinous processes over the contact surface; and

c. a wedge-like wing extending from and continuous with one end of the spacer to maintain lateral placement of the spacer.

12. The implant of claim 11 wherein the spacer is rotatable.

13. The implant of claim 11 wherein the spacer is rotatable relative to said wing.

14. The implant of claim 11 wherein the first wing is provided at an obtuse angle to the spacer.

15. The implant of claim 11 wherein the spacer can rotate relative to the wing and the distraction guide.

16. The implant of claim 11 wherein the first wing has a posterior end and an anterior end, and the posterior end does not extend as far beyond the posterior end of the spacer as the anterior end extends anteriorly to the anterior end of the spacer.

17. The implant of claim 11 wherein the cross-sectional shape of the spacer is selected from the group consisting of tear-drop, wedge, ellipse, and oval.

18. An implant for relieving pain associated with adjacent cervical vertebrae of the spine, that have a range of rotation relative to each other in a scissor-like motion, which implant is positionable between the spinous processes of adjacent cervical vertebrae, the implant comprising:

a. a wedge-shaped spacer;

b. a wedge-shaped first wing connected with the spacer;

c. a wedge-shaped distraction guide, the distraction guide extending from the spacer at the end distal to the first wing; and

d. a wedge-shaped second wing that connects with the spacer.

19. The implant in claim 18 wherein the spacer has a cross-sectional shape selected from the group consisting of tear-drop, wedge, ellipse, and oval.

20. The implant of claim 18 wherein the first wing has a posterior end and an anterior end, and the posterior end does not extend as far beyond the posterior end of the spacer as the anterior end extends anteriorly to the anterior end of the spacer.

21. The implant of claim 18 wherein the spacer is rotatable.

22. The implant of claim 18 wherein the second wing has a tongue extending therefrom for use in securing the second wing to the spacer.

23. The implant of claim 22 wherein portions of the tongue extending from the second wing define a bore;

wherein the spacer has a bore compatible with the bore through the tongue; and

a fastener compatible with the bore of the spacer and the bore through the tongue and that can secure the second wing to the spacer.

24. The implant in claim 23 wherein the second wing has an anterior side and a posterior side.

25. The implant in claim 18 wherein the posterior side of the first wing and the posterior side of the second wing extend no further than the posterior side of the spacer in a posterior direction.

26. The implant in claim 13 wherein the first wing and the second wing have an anterior side and a posterior side, and the anterior side of the first wing and of the second wing are angled outward relative to each other to accommodate the anatomy of the adjacent spinous processes of the cervical spine.

27. The implant of claim 18 wherein the spacer has an indentation and the second wing includes an exterior that can made with the indentation.

28. The implant of claim 18 wherein said second wing has an indentation and the spacer has an extension that can mate with the indentation of the second wing.

29. The implant of claim 18 wherein a hole of the second wing allows the second wing to be received over the distraction guide to connect with the spacer toward the end of the spacer adjacent to the distraction guide.

30. The implant of claim 18 wherein the hinge has a protrusion at an end of the hinge furthest from the lip.

31. The implant of claim 18 including a member for securing the second wing to the spacer when the second wing is received over the distraction guide onto the spacer and adjacent to the distraction guide.

32. A device for relieving pain associated with the vertebrae of the cervical spine and surrounding tissues and structures, by maintaining and/or adding distraction between adjacent cervical vertebrae when positioned between the spinous processes of adjacent cervical vertebrae, without detracting from the rotation of the cervical vertebrae relative to each other, the implant comprising:

a. a wedge-shaped spacer;

b. a bore in the spacer;

c. a wedge-shaped first wing attached at one end of a longitudinal axis of the spacer;

d. a wedge-shaped distraction guide at the end of the longitudinal axis of the spacer distal to the first wing;

e. a wedge-shaped second wing that is separate from the spacer, distraction guide, and first wing, and is received over the distraction guide and attached to the spacer during surgery after the distraction guide, spacer, and first wing are positioned;

f. a tongue extending from the second wing;

g. a bore through the tongue of the second wing; and

h. a fastener to join and hold the second wing to the spacer once the second wing is received over the distraction guide and the bore of the tongue of the second wing and the bore of the spacer are aligned.

33. The implant of claim 32 wherein the spacer is rotatably connected with the first wing, the second wing, and the distraction guide.

34. An implant for relieving pain associated with the vertebrae of the cervical spine and surrounding tissues and structures, by maintaining and/or adding distraction between adjacent cervical vertebrae when positioned between the spinous processes of adjacent cervical vertebrae, without detracting from rotation of the cervical vertebrae relative to each other, the implant comprising:

a. a wedge-shaped spacer;

b. a wedge-shaped first wing extending from one end of the longitudinal axis of the spacer;

c. a wedge-shaped distraction guide extending from the end of the longitudinal axis of the spacer distal to the first wing;

d. a wedge-shaped second wing separate from the spacer, distraction guide, and first wing that is attached to the spacer at the end of the longitudinal axis of the spacer distal to the first wing during surgery, after positioning the distraction guide, spacer and first wing; and

e. a system to secure the second wing to the spacer.

35. An implant for relieving pain associated with the vertebrae of the cervical spine and surrounding tissues and structures, by maintaining and/or adding distraction between adjacent cervical vertebrae when positioned between the spinous processes of adjacent cervical vertebrae, without detracting from rotation of the cervical vertebrae relative to each other, the implant comprising:

a. a wedge-shaped spacer with a longitudinal axis, which spacer maintains and/or adds distraction when positioned between the spinous processes of adjacent cervical vertebrae;

b. a wedge-shaped distraction guide at one end of the longitudinal axis of the spacer to introduce distraction between the spinous processes of adjacent cervical vertebrae prior to insertion and positioning of the spacer;

c. a wedge-shaped first wing at the end of the longitudinal axis distal to the distraction guide to maintain lateral positioning of the implant; and

d. a keep ring placed around the spinous processes in the way of backward displacement of the implant.

36. A method for implanting an implant between the spinous processes of cervical vertebrae comprising the steps of:

inserting a first portion of the implant including a spacer and a distraction end laterally;

inserting a second portion of the implant including a wing laterally from an opposite direction from the insertion of the first portion; and

fastening the second portion to the first portion.

37. The method of claim 36 wherein the fastening step includes interference-fitting the second portion onto the first portion.

38. The method of claim 36 wherein the fastening step includes applying a fastener to the second and the first portion along a posterior to anterior direction.

39. The method of claim 36 wherein the fastening step includes causing a protrusion of one of the first portion and the second portion to mate with an indentation of the other of the first portion and the second portion.

40. The method of claim 36 including implanting the implant without severing the *ligamentum nuchae*.

41. The method of claim 36 including implanting the implant without altering the spinous processes.

42. A device that can relieve pain associated with the spine and the tissues surrounding the spine comprising:

a first wing;

a spacer;

a distraction guide;

wherein said spacer is elongated in cross-section and said first wing is elongated in cross-section in the same direction that said spacer is elongated; and

said distraction guide extends from said spacer.

43. The device of claim 42 wherein said first wing and said spacer are wedge-shaped in cross-section.

44. The device of claim 42 wherein said first wing and said spacer are wedge-shaped in cross-section with the wedge shape of the first wing points in about the same direction as the wedge shape of the spacer.

45. The device of claim 43 including a second wing that is wedge-shaped.

46. The device of claim 42 including a second wing having an aperture that is shaped to be received over the distraction guide.

47. The device of claim 42 wherein said distraction guide extends from the spacer and the second wing has an aperture that is shaped to be received over the distraction guide and engaged with the spacer.

48. The device of claim 42 wherein said first wing is elliptical in shape and the spacer is wedge-shaped.

49. The device of claim 48 wherein said second wing is elliptical in shape.

50. The device of claim 42 wherein said spacer is rotatable.

51. The device of claim 42 wherein said spacer is rotatably mounted relative to the first wing and the distraction guide.

52. The device of claim 42 wherein said first wing has an anterior end and a posterior end and the anterior end extends past the spacer and the posterior end ends with the spacer.

53. The device of claim 42 wherein said first wing has an anterior end and a posterior end and the anterior end extends past the spacer and the posterior end does not extend past the spacer.

54. The device of claim 42 wherein said first wing has an anterior end and a posterior end and the anterior end extends past the spacer and the posterior end is truncated.

55. The device of clam 52 including a second wing and the second wing has an anterior end and a posterior end and the anterior end extends past the spacer and the posterior end ends with the spacer.

56. The device of claim 53 including a second wing and the second wing has an anterior end and a posterior end and the anterior end extends past the spacer and the posterior end does not extend past the spacer.

57. The device of claim 54 including a second wing and the second wing has an anterior end and a posterior end and the anterior end extends past the spacer and the posterior end is truncated.

58. The device of claim 42 including a second wing, and wherein said first and second wings diverge from each other.

59. The device of claim 42 including a second wing, and wherein said first and second wings are positioned at obtuse angles to the spacer.

60. The device of claim 42 including a second wing and wherein said first and second wings have anterior ends that are directed toward an anterior of a patient and wherein said anterior ends diverge from each other.

61. The device of claim 42 including a keep that is adapted for being secured to a spinous process in order to block motion of the spacer in a posterior direction.

62. The method of claim 36 including implanting the implant without severing the supraspinous ligament.

63. The device of claim 42 wherein the first wing is selected from the group consisting of wedge-shaped, elliptical-shaped, tear drop and ovoid-shaped.

64. The device of claim 42 including a second wing that can fit over the distraction guide, which is selected from the group consisting of wedge-shaped, elliptical-shaped, tear-drop shaped and ovoid shaped.

65. The device of claim 42 wherein said spacer is selected from the group consisting of any wedge-shaped, elliptical-shaped, tear drop shaped and ovoid shaped.

66. An interspinous implant adapted to be inserted between spinous processes, the implant comprising:

a body adapted to be inserted between the spinous processes, the body including a first part and a second part; and

a distracting insert to cojoin and distract apart the first part and the second part.

67. The interspinous implant of claim 66, wherein said body includes a distraction guide.

68. The interspinous implant of claim 67, wherein said body includes a first wing located distally from said distraction guide.

69. The interspinous implant of claim 66, further comprises:

one or more inserts extending from said distracting insert; and

one or more cavities within said body; said one or more cavities adapted to receive said one or more inserts;

wherein said one or more cavities includes a first groove formed in said first part and a second groove formed in said second part.

70. The interspinous implant of claim 69, wherein a height of said one or more inserts is larger than a height of a respective cavity, such that when said one or more inserts is received in the respective cavity, said first part and said second part are urged apart.

71. The interspinous implant of claim 66, wherein:

said distracting insert includes a clip, the clip having a first tab and a second tab; and

when said distracting insert is seated in said body, said clip resists relative movement between said distracting insert and said body.

72. The interspinous implant of claim 68, further comprising:

a second wing adapted to be connected with said body so that a portion of the spinous processes are positioned between said first wing and said second wing.

73. The interspinous implant of claim 66, wherein:

said body comprises one of a biocompatible thermoplastic and a surgical grade metal; and

said distracting insert comprises one of a biocompatible thermoplastic and a surgical grade metal.

74. The interspinous implant of claim 66, further comprising:

one or more alignment features extending from one of said first part and said second part; and

one or more receiving features corresponding to said one or more alignment features formed in the other of said first part and said second part and adapted to receive said one or more alignment features.

75. The interspinous implant of claim 74, wherein said one or more alignment features are one or more pins, and said one or more receiving features are one or more holes.

76. The interspinous implant of claim 67, wherein said distraction guide is wedge-shaped.

77. An interspinous implant adapted to be inserted between spinous processes, the implant comprising:

a body adapted to be inserted between the spinous processes, the body including a first part and a second part;

a distracting insert to cojoin the first part and the second part.

78. The interspinous implant of claim 77, wherein said body includes a distraction guide.

79. The interspinous implant of claim 78, wherein said body includes a first wing located distally from said distraction guide.

80. The interspinous implant of claim 77, further comprises:

one or more inserts extending from said distracting insert; and

one or more cavities within said body; said one or more cavities adapted to receive said one or more inserts;

wherein said one or more cavities includes a first groove formed in said first part and a second groove formed in said second part.

81. The interspinous implant of claim 77, wherein:

said distracting insert includes a clip, the clip having a first tab and a second tab; and

when said distracting insert is seated in said body, said clip resists relative movement between said distracting insert and said body.

82. The interspinous implant of claim 79, further comprising:

a second wing adapted to be connected with said body so that a portion of the spinous processes are positioned between said first wing and said second wing.

83. The interspinous implant of claim 77, wherein:

said body comprises one of a biocompatible thermoplastic and a surgical grade metal; and

said distracting insert comprises one of a biocompatible thermoplastic and a surgical grade metal.

84. The interspinous implant of claim 77, further comprising:

one or more alignment features extending from one of said first part and said second part; and

one or more receiving features corresponding to said one or more alignment features formed in the other of said first part and said second part and adapted to receive said one or more alignment features.

85. The interspinous implant of claim 84, wherein said one or more alignment features are one or more pins, and said one or more receiving features are one or more holes.

86. The interspinous implant of claim 78, wherein said distraction guide is wedge-shaped.

87. An interspinous implant adapted to be inserted between spinous processes, the implant comprising:

a body adapted to be inserted between the spinous processes, the body including a first part and a second part;

a distracting insert to distract apart the first part and the second part.

88. The interspinous implant of claim 87, wherein said body includes a distraction guide.

89. The interspinous implant of claim 88, wherein said body includes a first wing located distally from said distraction guide.

90. The interspinous implant of claim 87, further comprises:

one or more inserts extending from said distracting insert; and

one or more cavities within said body; said one or more cavities adapted to receive said one or more inserts;

wherein said one or more cavities includes a first groove formed in said first part and a second groove formed in said second part.

91. The interspinous implant of claim 90, wherein a height of said one or more inserts is larger than a height of a respective cavity, such that when said one or more inserts is received in the respective cavity, said first part and said second part are urged apart.

92. The interspinous implant of claim 89, further comprising:

a second wing adapted to be connected with said body so that a portion of the spinous processes are positioned between said first wing and said second wing.

93. The interspinous implant of claim 87, wherein:

said body comprises one of a biocompatible thermoplastic and a surgical grade metal; and

said distracting insert comprises one of a biocompatible thermoplastic and a surgical grade metal.

94. The interspinous implant of claim 87, further comprising:

one or more alignment features extending from one of said first part and said second part; and

one or more receiving features corresponding to said one or more alignment features formed in the other of said first part and said second part and adapted to receive said one or more alignment features.

95. The interspinous implant of claim 94, wherein said one or more alignment features are one or more pins, and said one or more receiving features are one or more holes.

96. The interspinous implant of claim 88, wherein said distraction guide is wedge-shaped.

97. An interspinous implant adapted to be inserted between spinous processes, the implant comprising:

a body adapted to be inserted between the spinous processes, the body including a first part and a second part;

a distracting insert to cojoin and distract apart the first part and the second part, the distracting insert including a clip; and

wherein when the distracting insert is seated within the body, the clip resists relative movement between the body and the distracting insert.

98. A system for distracting adjacent spinous processes, comprising:

a plurality of bodies, each of the bodies having a first part and a second part; and

a distracting insert to cojoin and distract apart the first part and the second part;

wherein at least one of the plurality of bodies has a different shape than at least one other of the plurality of bodies.

99. The system of claim 98, wherein each body includes a first wing; and

the system further comprising:

a plurality of second wings, each second wing connectable with said body such that a portion of the spinous processes are positioned between the first wing and the second wing;

wherein each of the plurality of second wings is sized according to a shape of a corresponding body.

100. A system for distracting adjacent spinous processes, comprising:

a body adapted to be inserted between the spinous processes, the body including a first part and a second part;

a plurality of distracting inserts to cojoin and distract apart the first part and the second part;

wherein at least one of the plurality of distracting inserts has a different distraction height than at least one other of the plurality of spacers.

101. The system of claim 100, wherein said body includes a first wing; and

the system further comprising:

a plurality of second wings, each second wing connectable with said body such that a portion of the spinous processes are positioned between the first wing and the second wing;

wherein each of the plurality of second wings is sized according to a distraction height of a corresponding distracting insert.

102. A system for distracting adjacent spinous processes, comprising:

a plurality of implants, each of the plurality of implants including a body having a first part and a second part;

wherein at least one of the plurality of bodies has a different shape than at least one other of the plurality of bodies;

a plurality of distracting inserts to cojoin and distract apart the first part and the second part;

wherein at least one of the plurality of distracting inserts has a different distraction height than at least one other of the plurality of spacers.

103. The system of claim 102, wherein each body includes a first wing; and

the system further comprising:

a plurality of second wings, each second wing connectable with said body such that a portion of the spinous processes are positioned between the first wing and the second wing;

wherein each of the plurality of second wings is sized according to a shape of a corresponding body and a distraction height of a corresponding distracting insert.

104. A method for insertion of an interspinous implant between spinous processes comprising the steps of:

accessing first and second spinous processes;

inserting a body between the spinous processes, which body includes a first part and a second part;

inserting a distracting insert between the first part and the second part in order to distract the first part and the second part apart and in order to cojoin the first part and the second part.

105. The method of claim 104, further comprising:

seating the distracting insert with the body; and

forming an interference fit between the distracting insert and the body.

106. A method for insertion of an interspinous implant between spinous processes comprising the steps of:

accessing first and second spinous processes;

inserting a body between the spinous processes, which body includes a first part and a second part;

inserting a distracting insert between the first part and the second part in order to cojoin the first part and the second part.

107. The method of claim 106, further comprising:

seating the distracting insert with the body; and

forming an interference fit between the distracting insert and the body.

108. A method for insertion of an interspinous implant between spinous processes comprising the steps of:

accessing first and second spinous processes;

inserting a body between the spinous processes, which body includes a first part and a second part;

inserting a distracting insert between the first part and the second part in order to distract the first part and the second part apart.

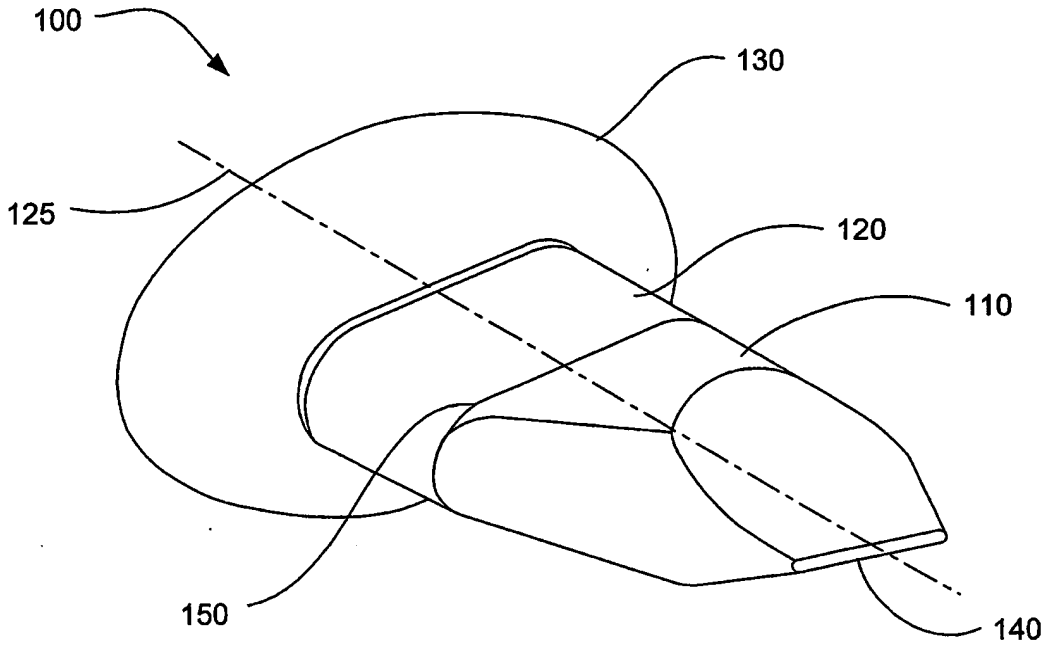



FIG. - 1

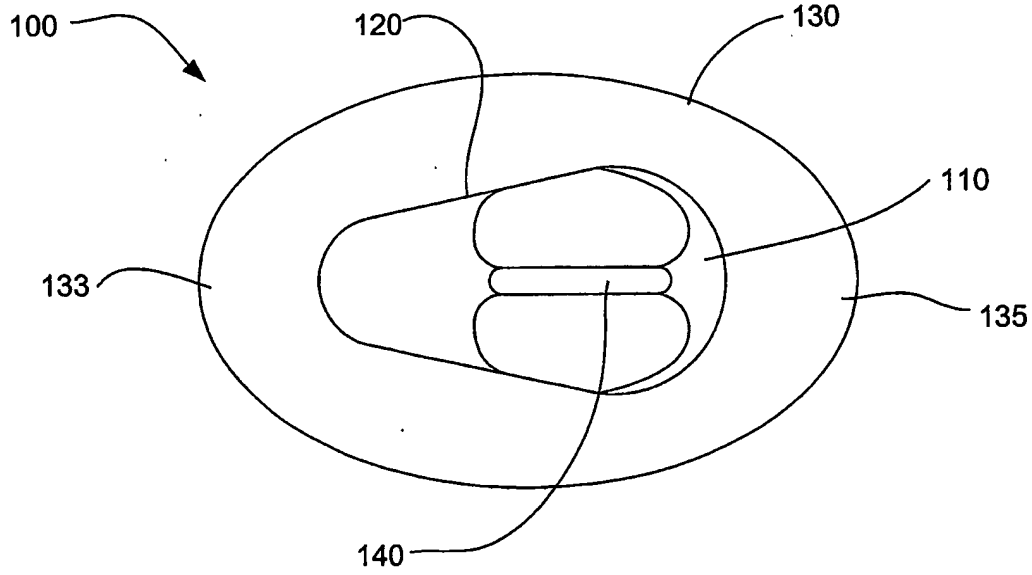



FIG. - 2

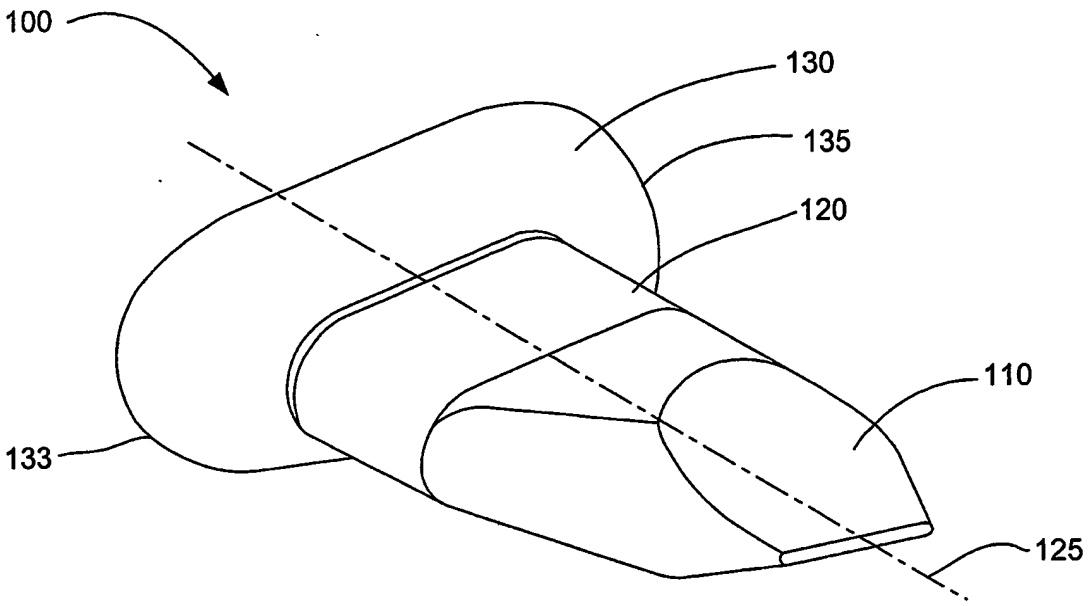



FIG. - 3

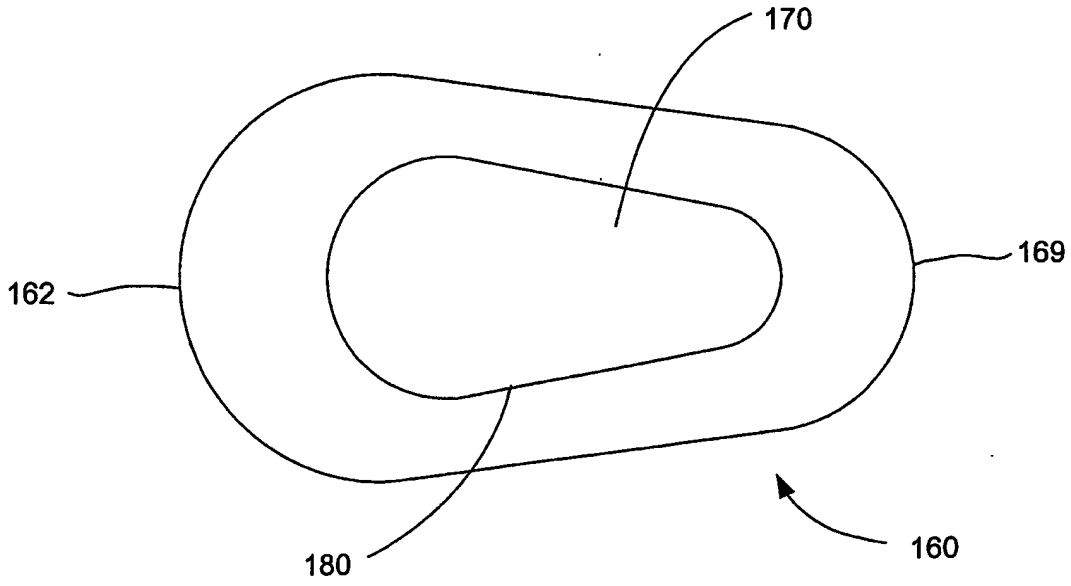



FIG. - 4

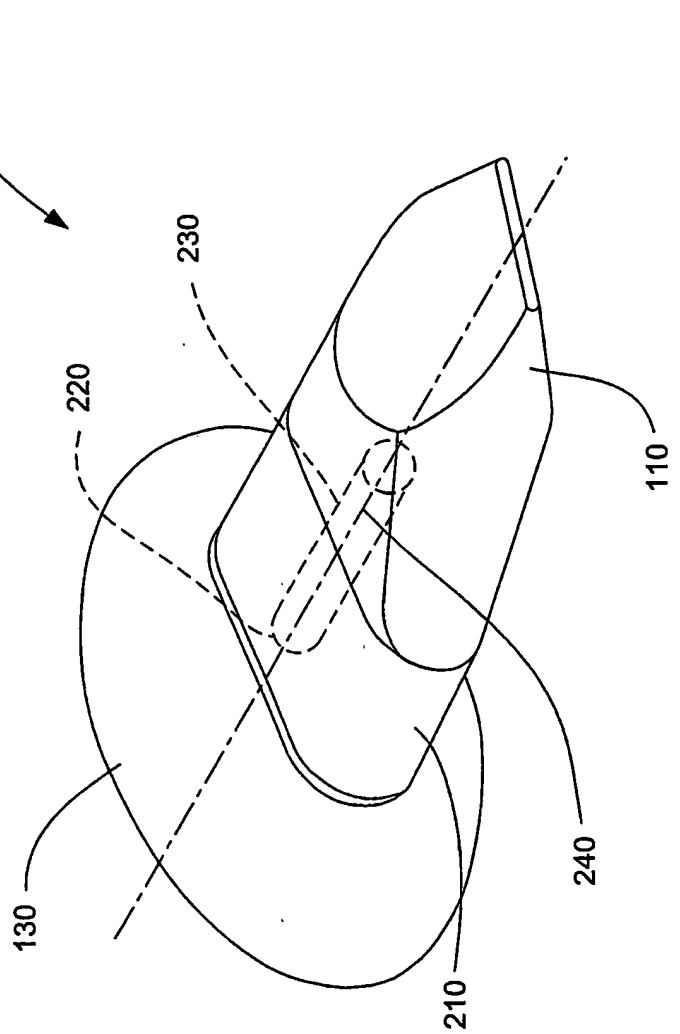



FIG. - 5

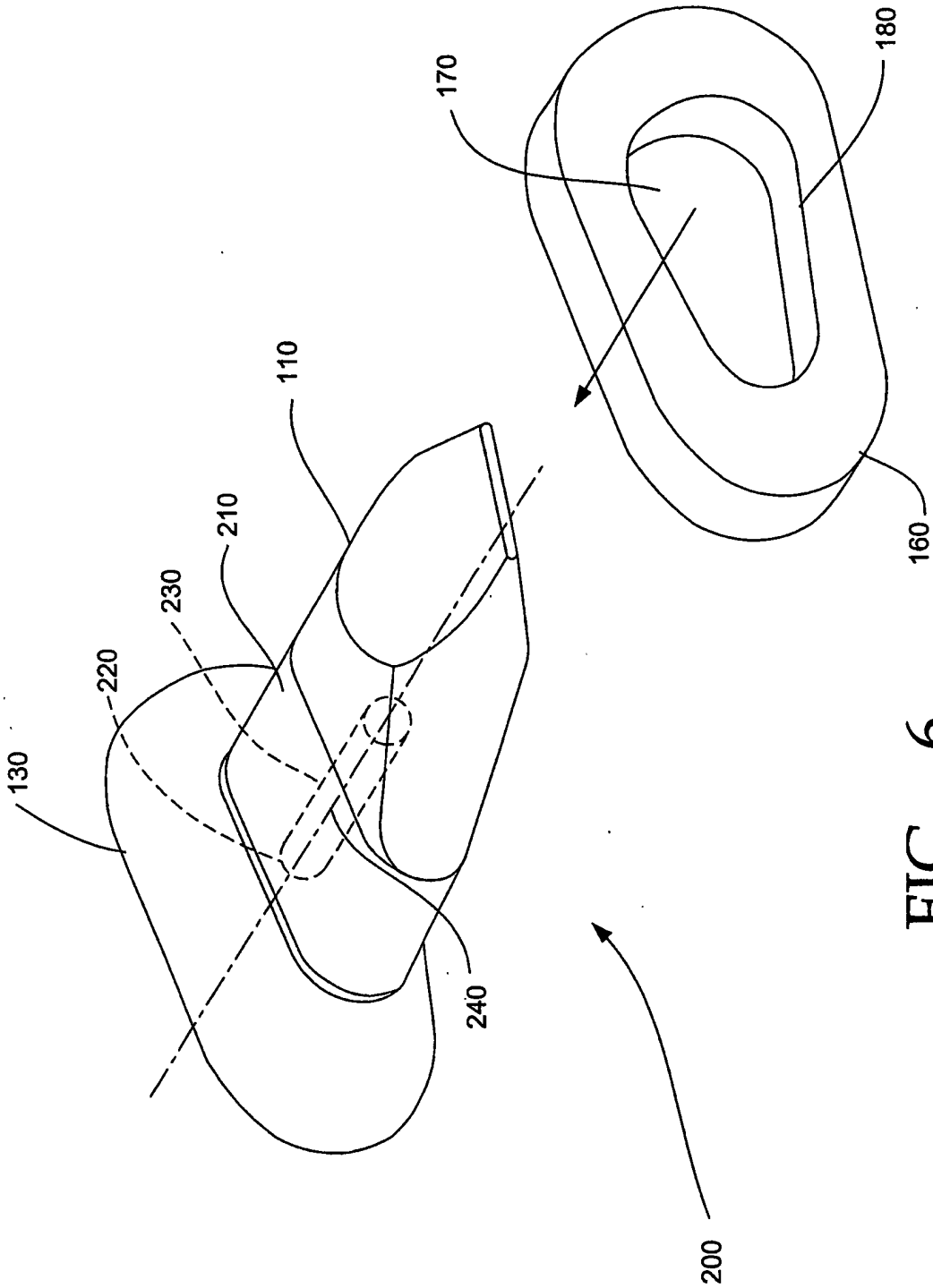



FIG. - 6

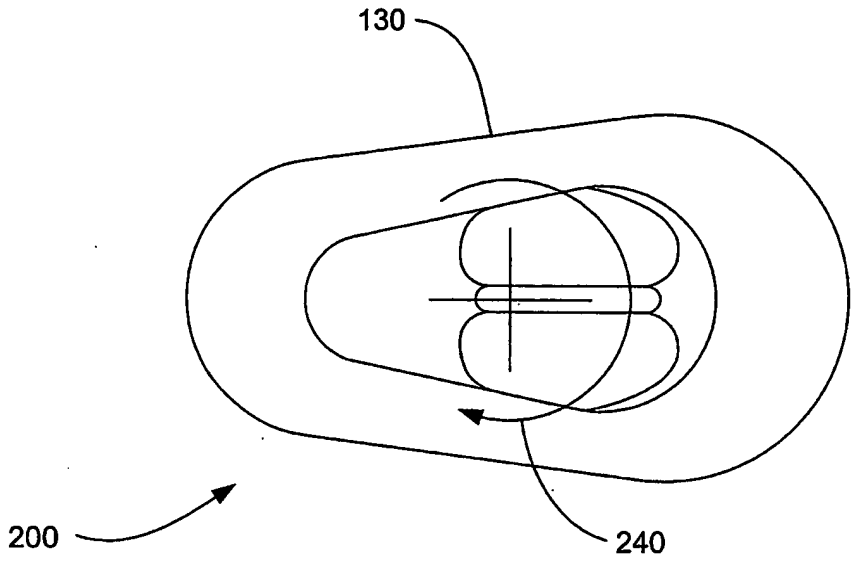



FIG. - 7

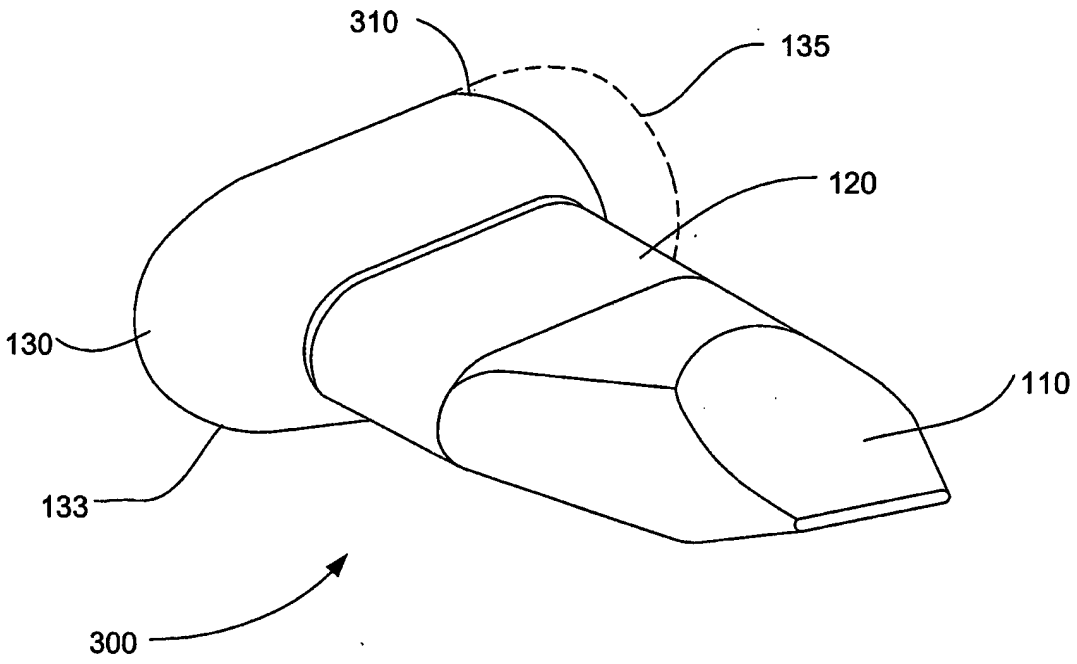



FIG. - 8

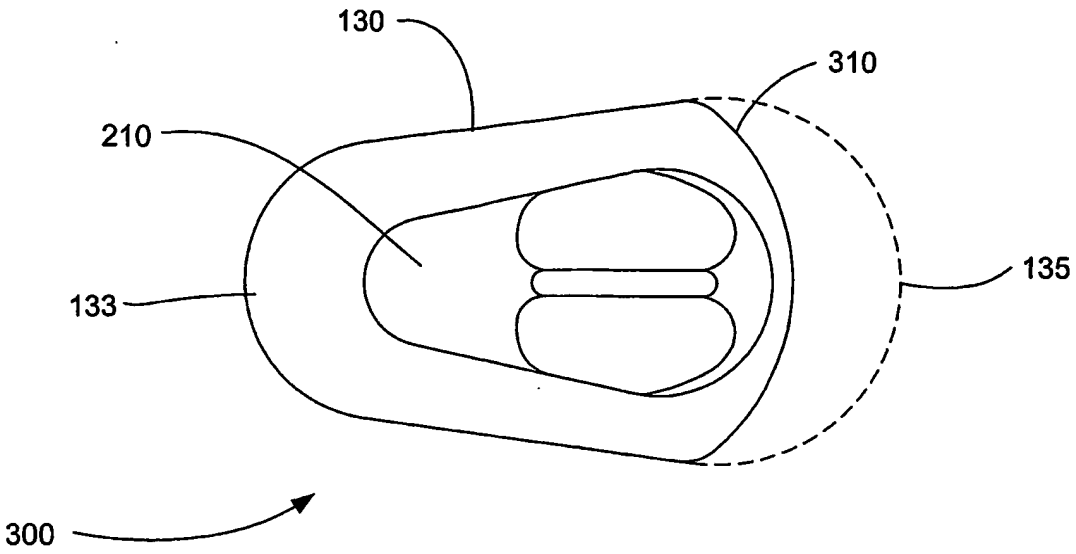



FIG. - 9a

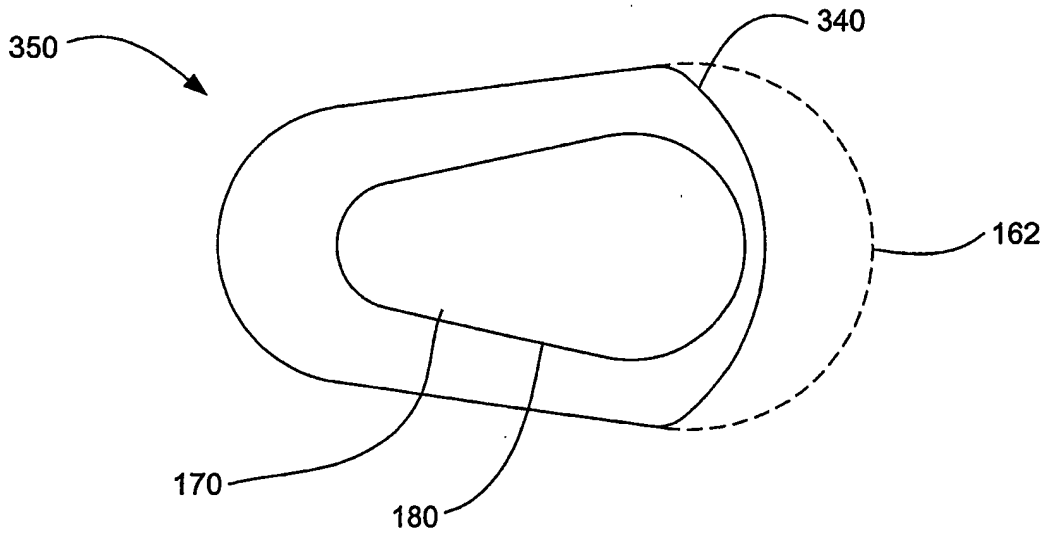



FIG. - 9b

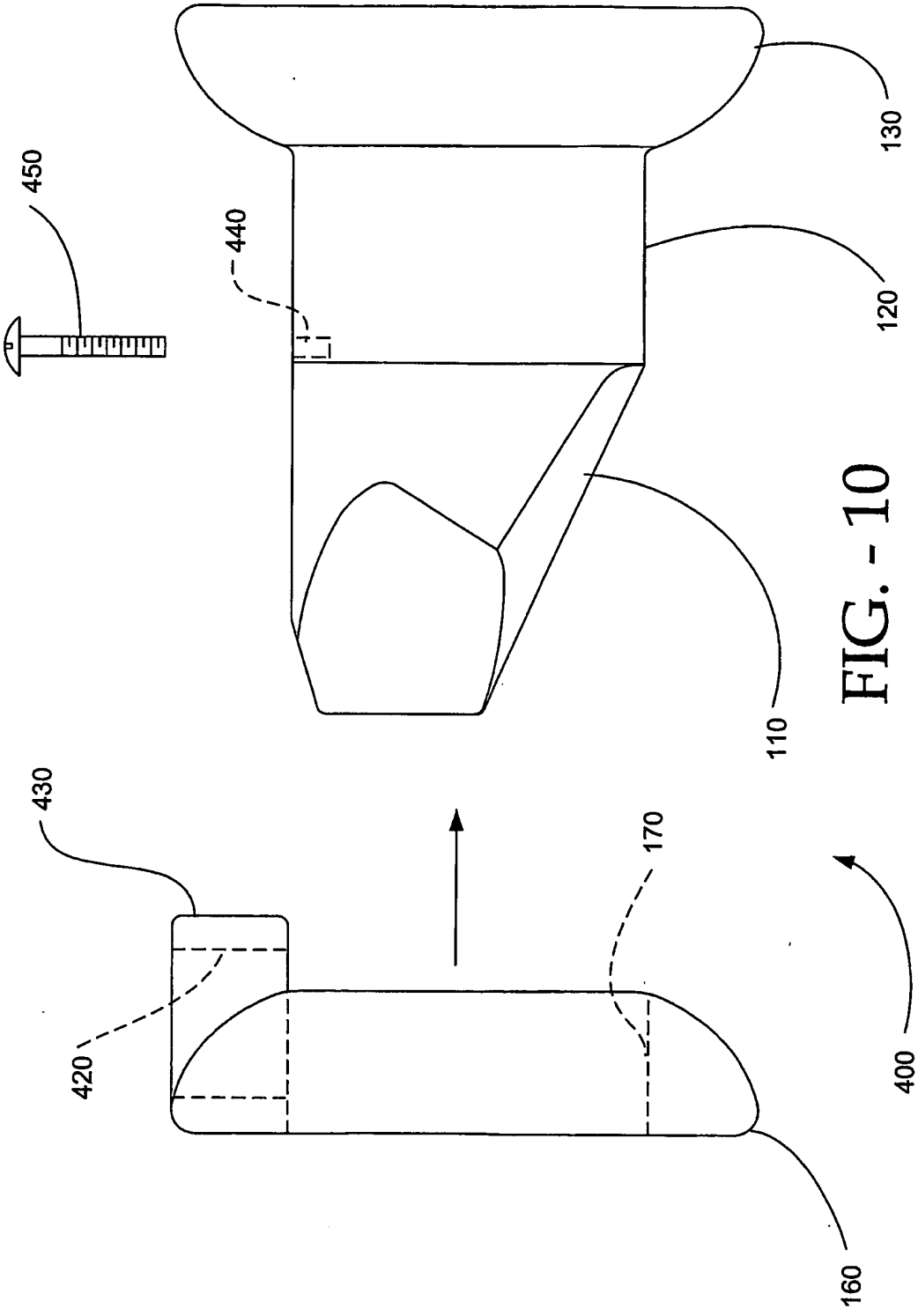
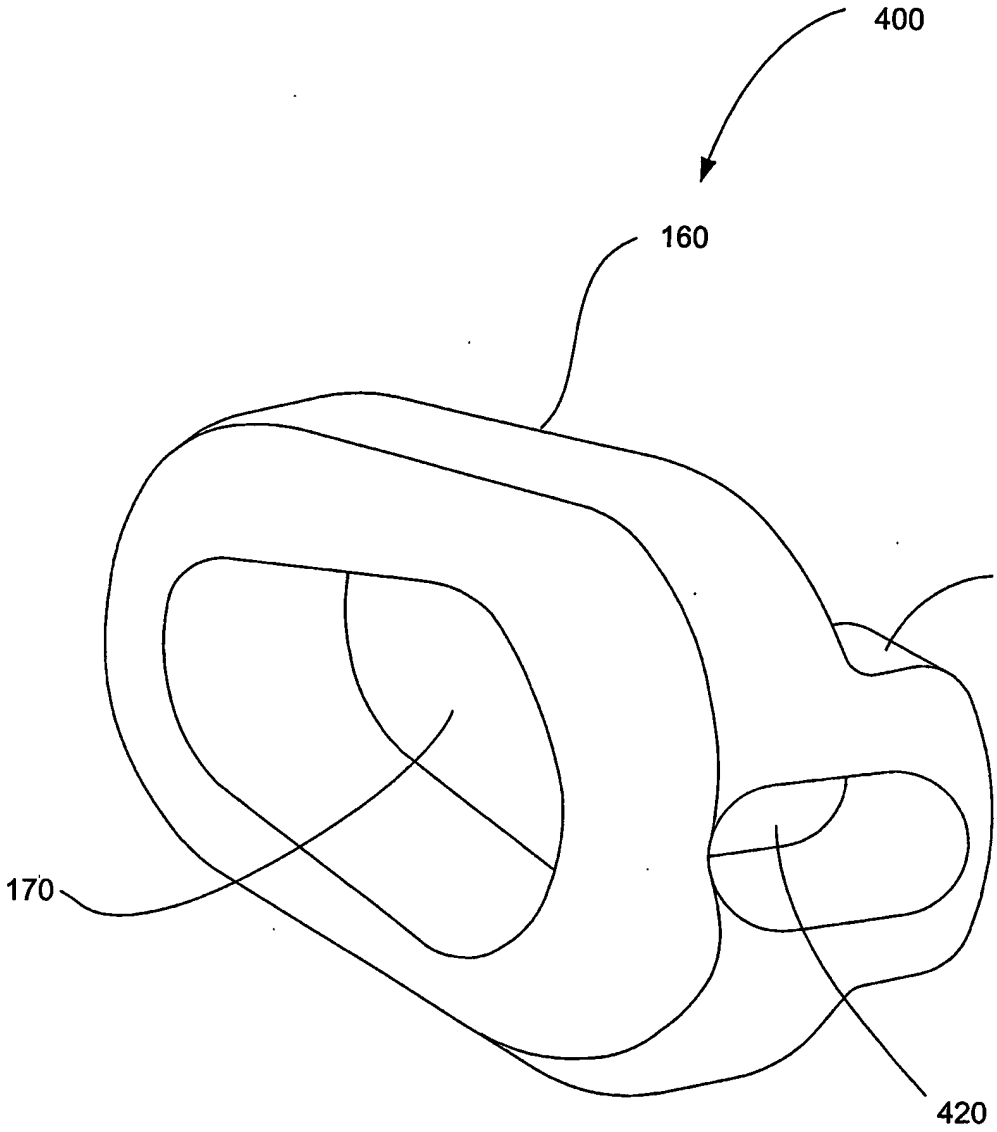



FIG. - 10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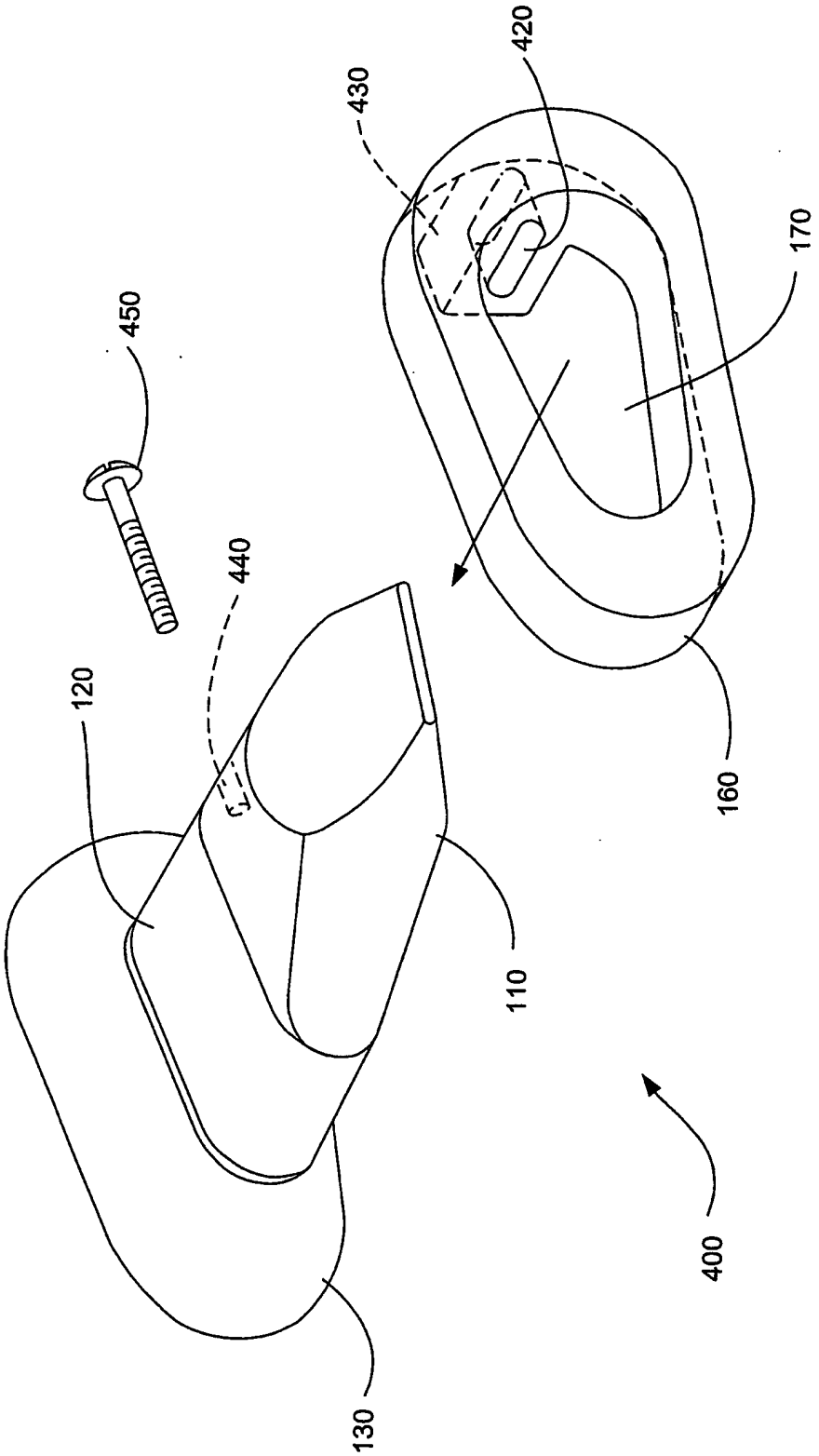



FIG. - 12

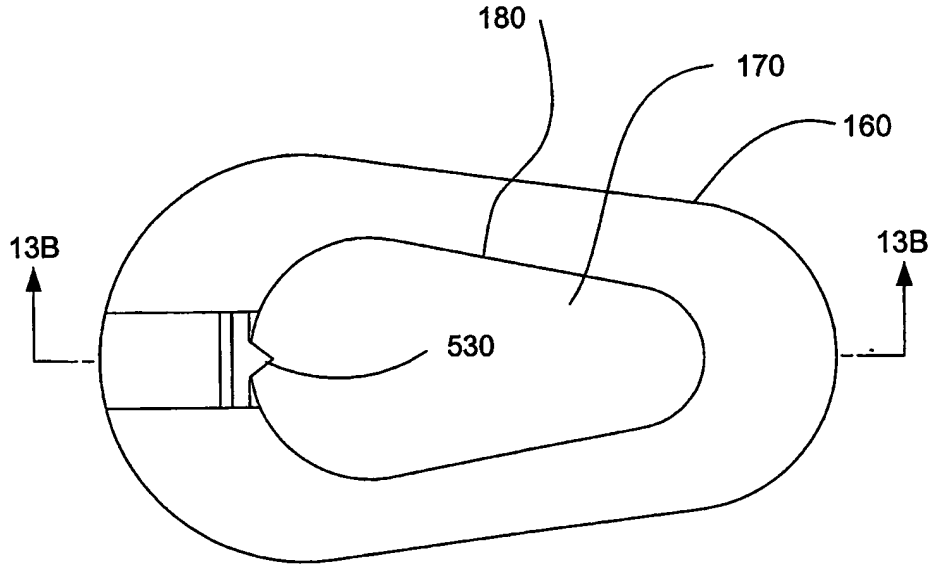



FIG. - 13A

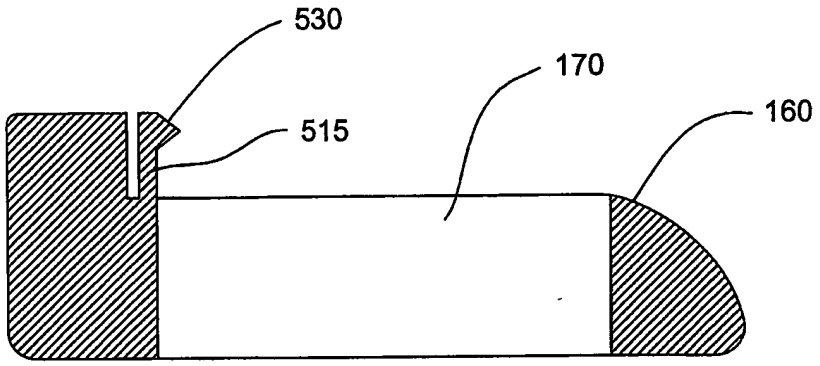



FIG. - 13B

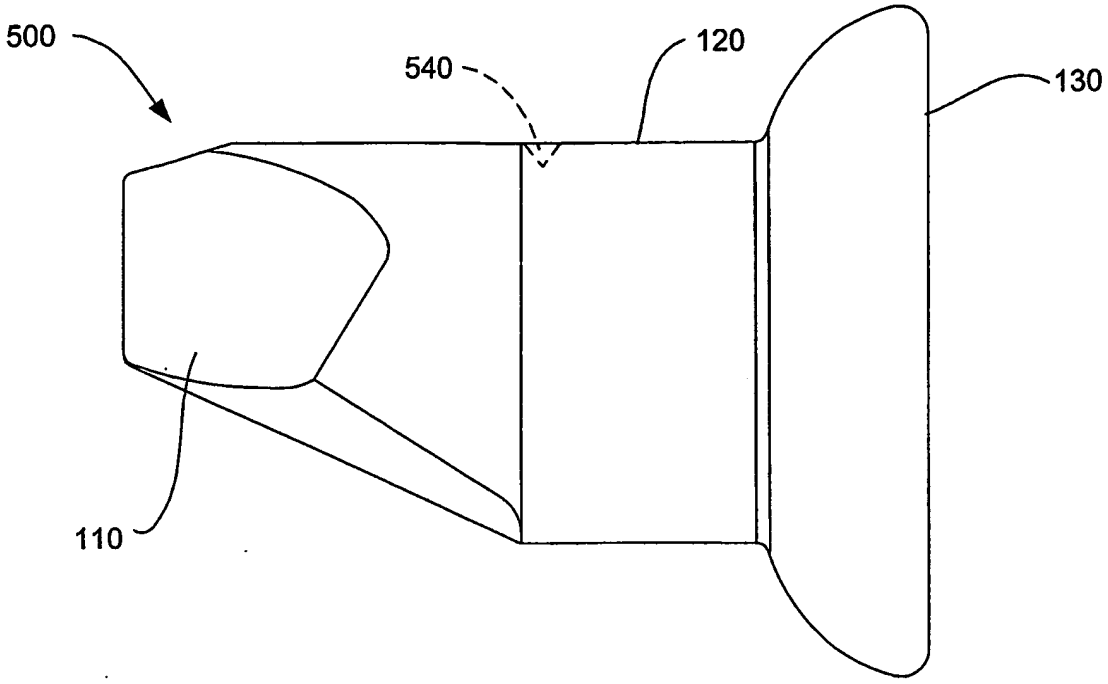



FIG. - 14A

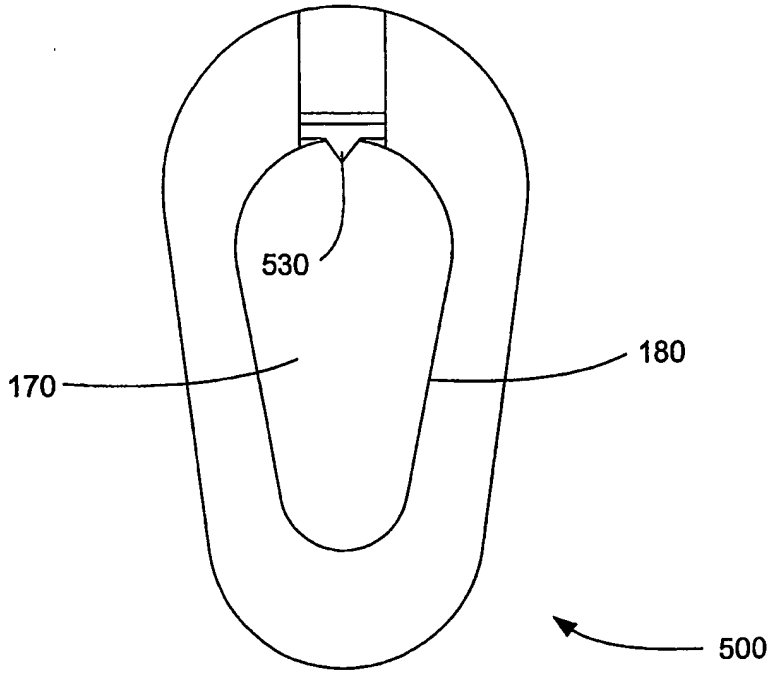



FIG. - 14B

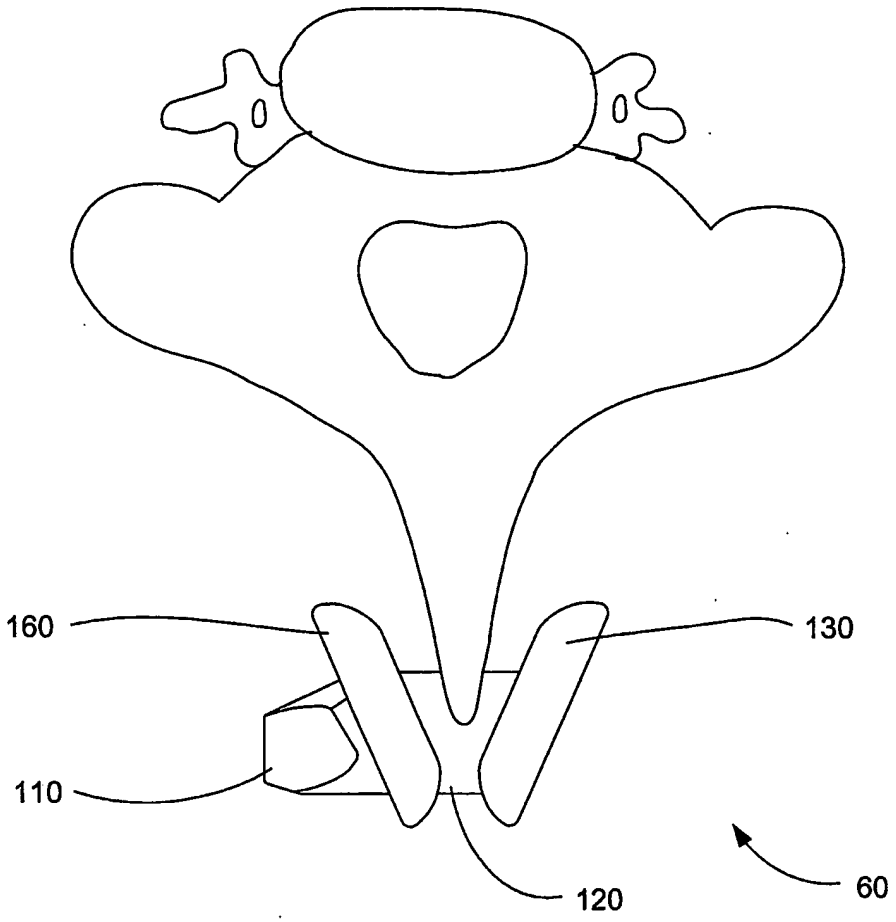
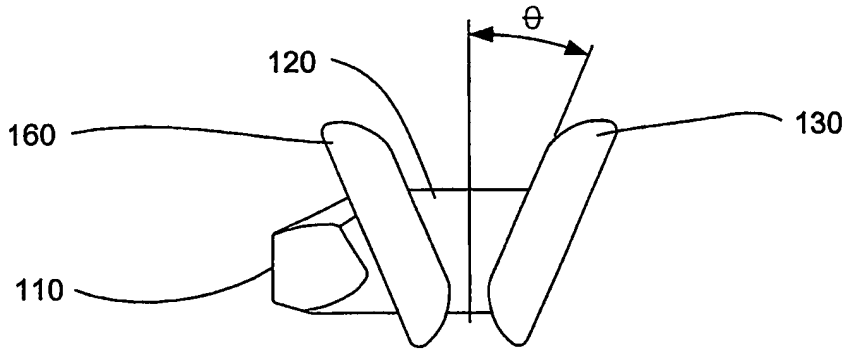



FIG. - 15A



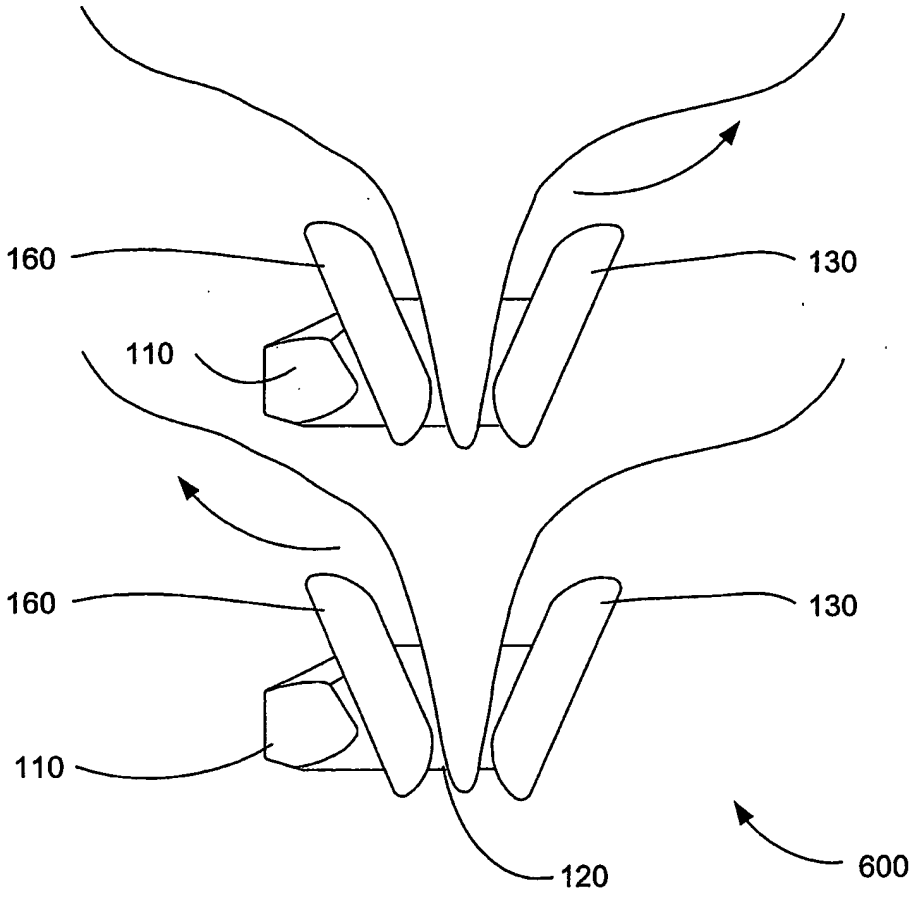



FIG. 16

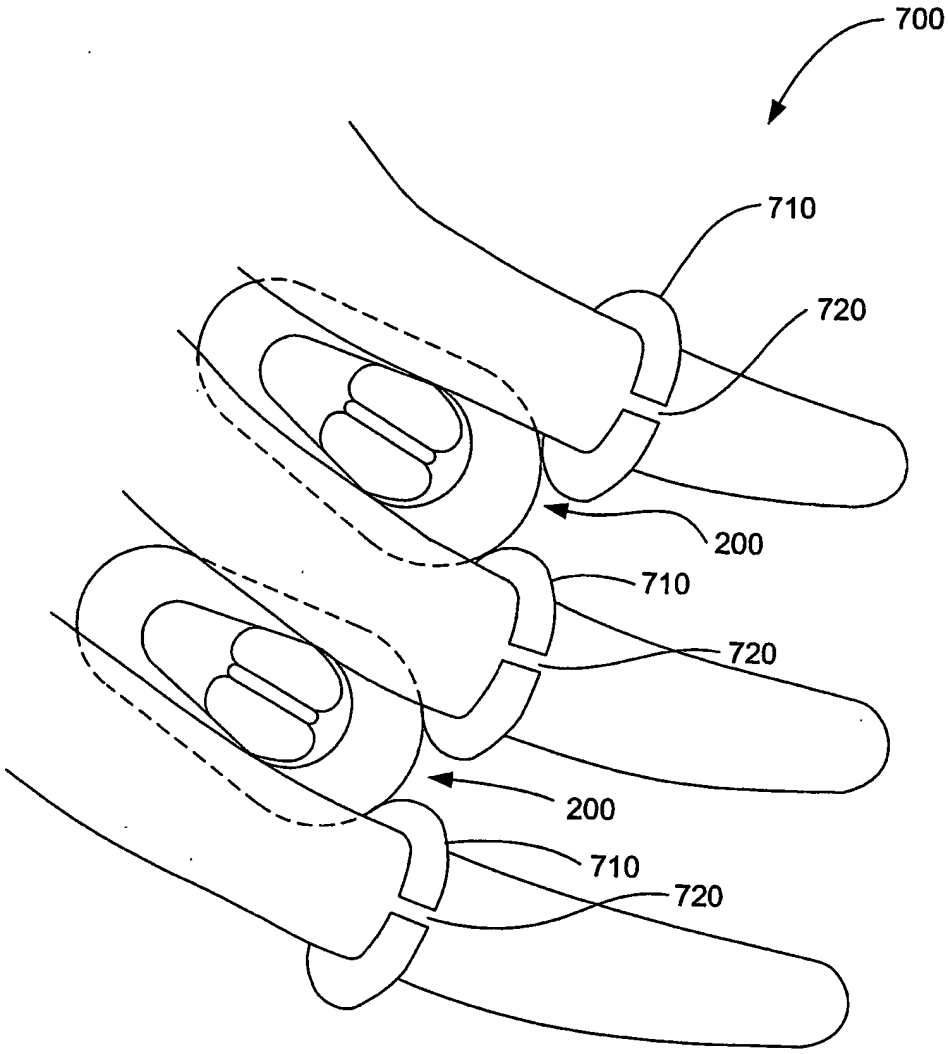



FIG. - 17

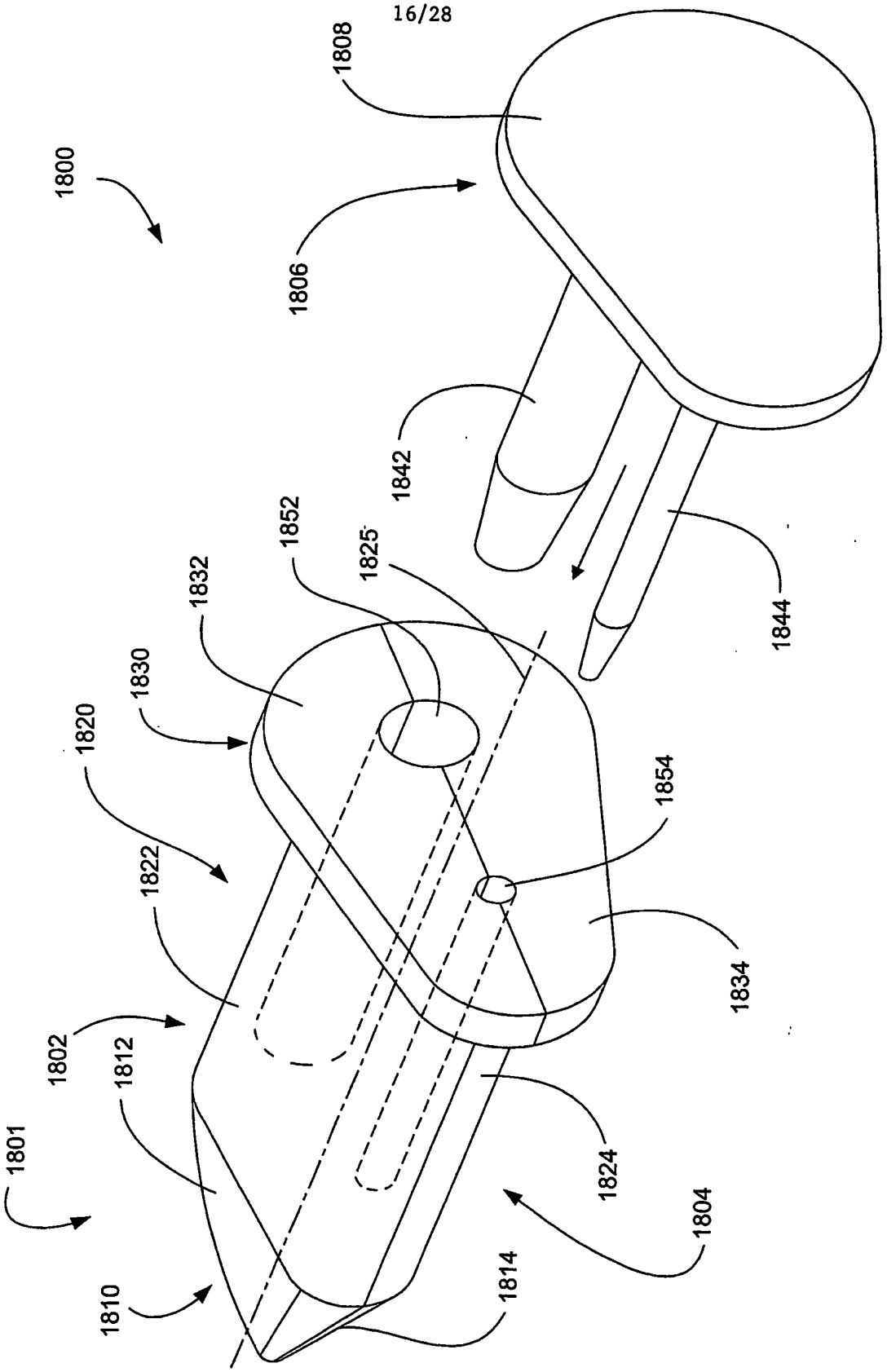

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FIG. - 18

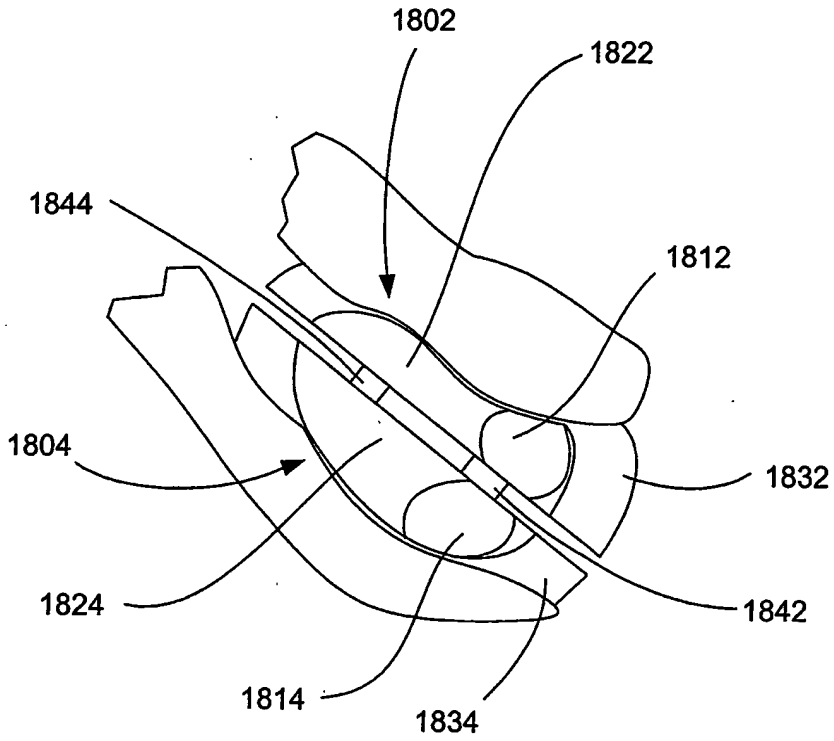


FIG. - 19A

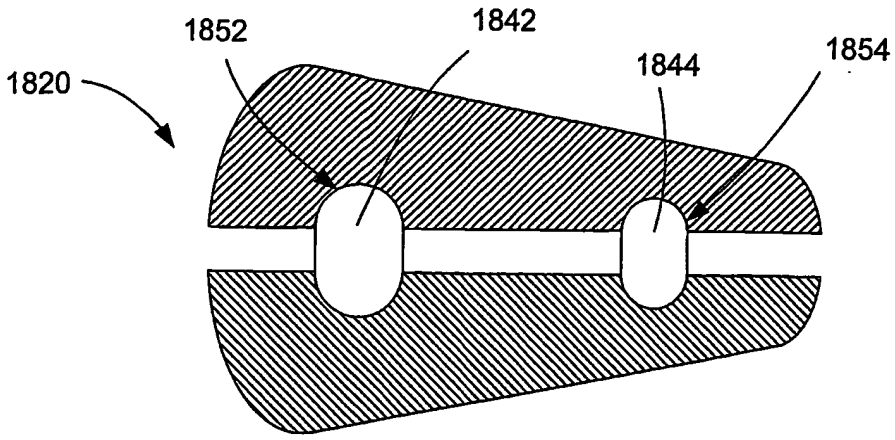


FIG. - 19b

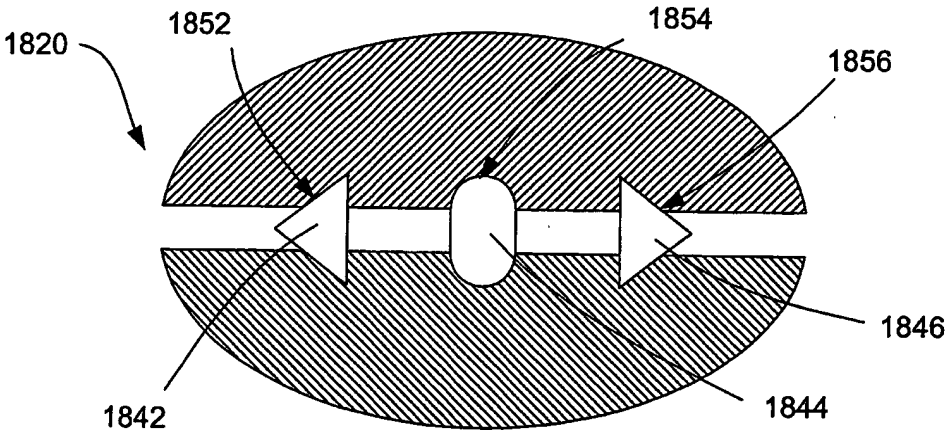


FIG. - 19c

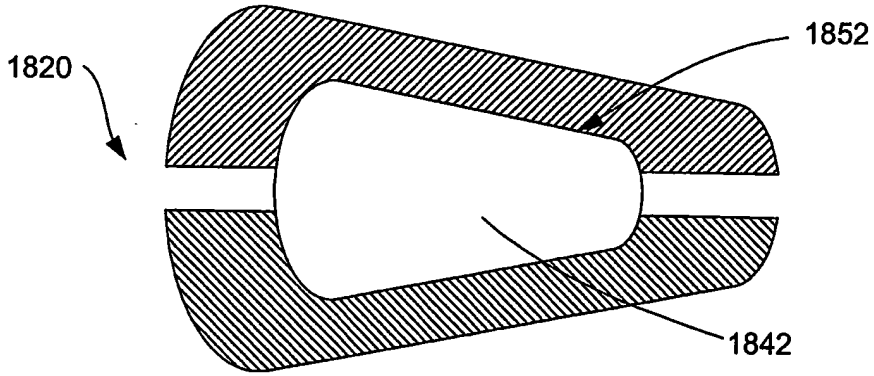


FIG. - 19d

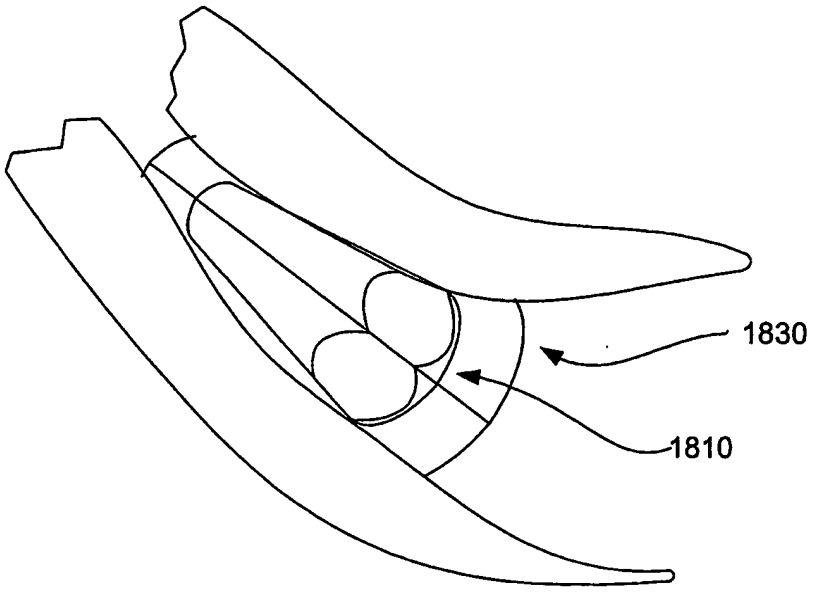


FIG. - 20A

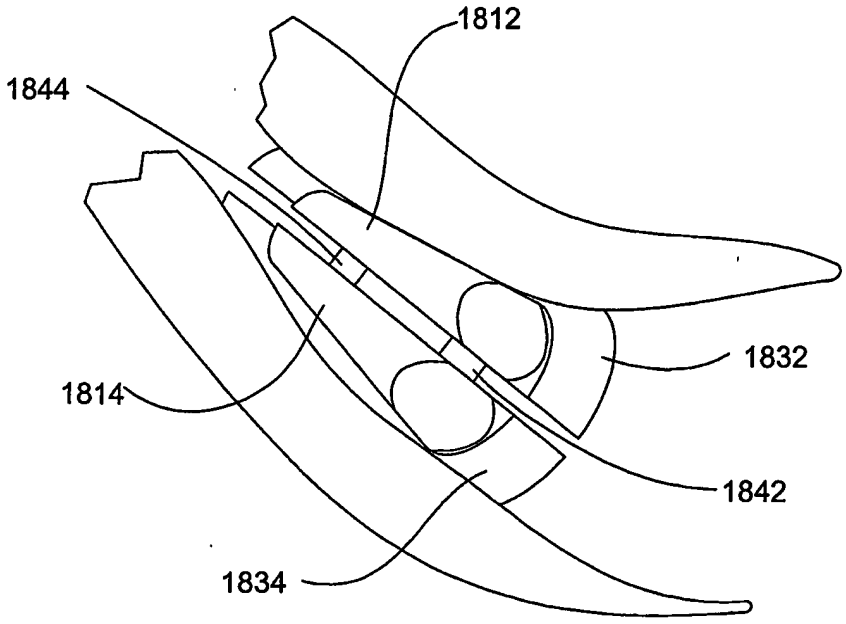


FIG. - 20B

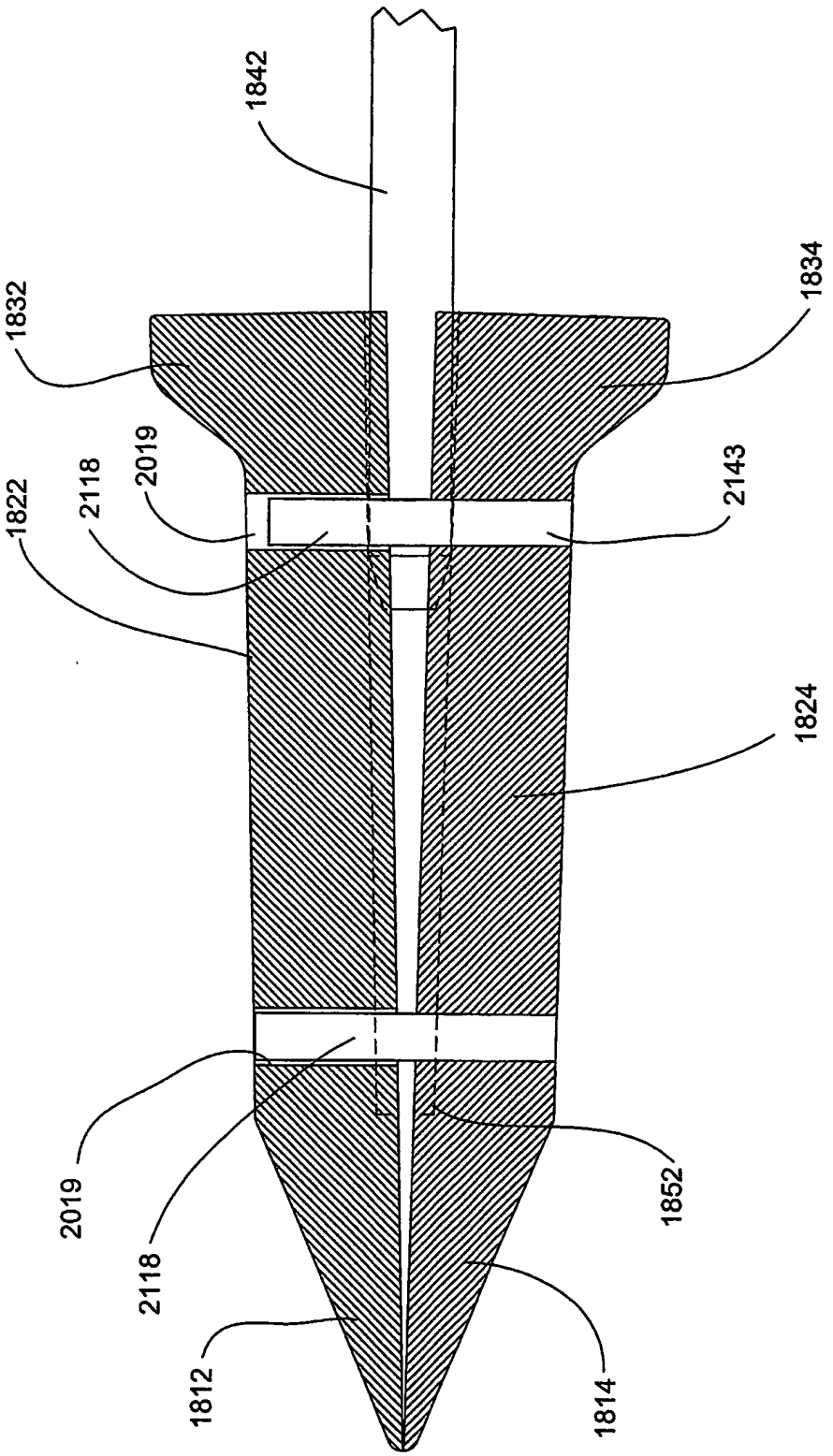
1842
1832
1834
2019
2118
1822
2143
1824
2019
2118
1852
1812
1814

FIG. - 21A

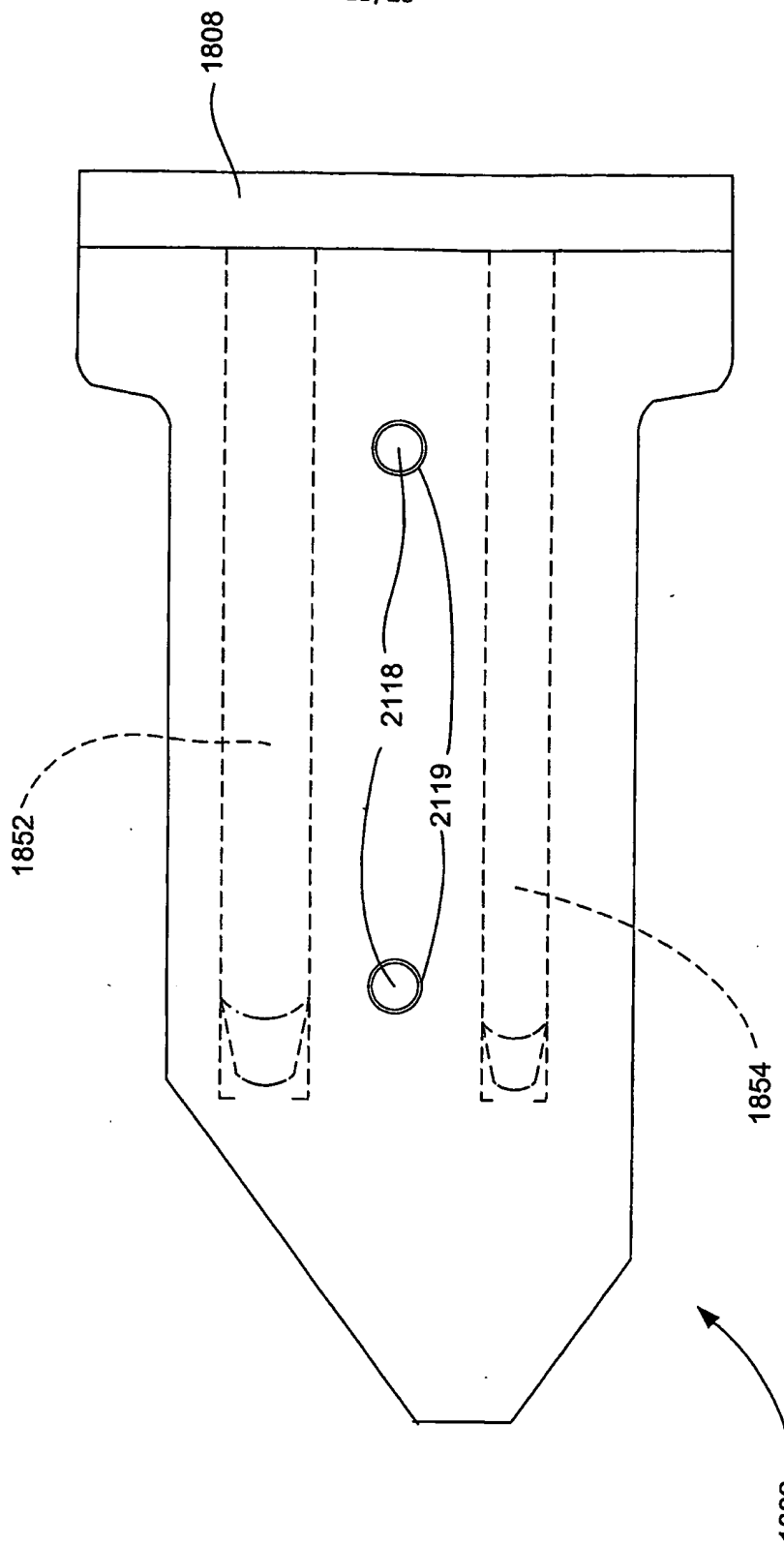


FIG. - 21B

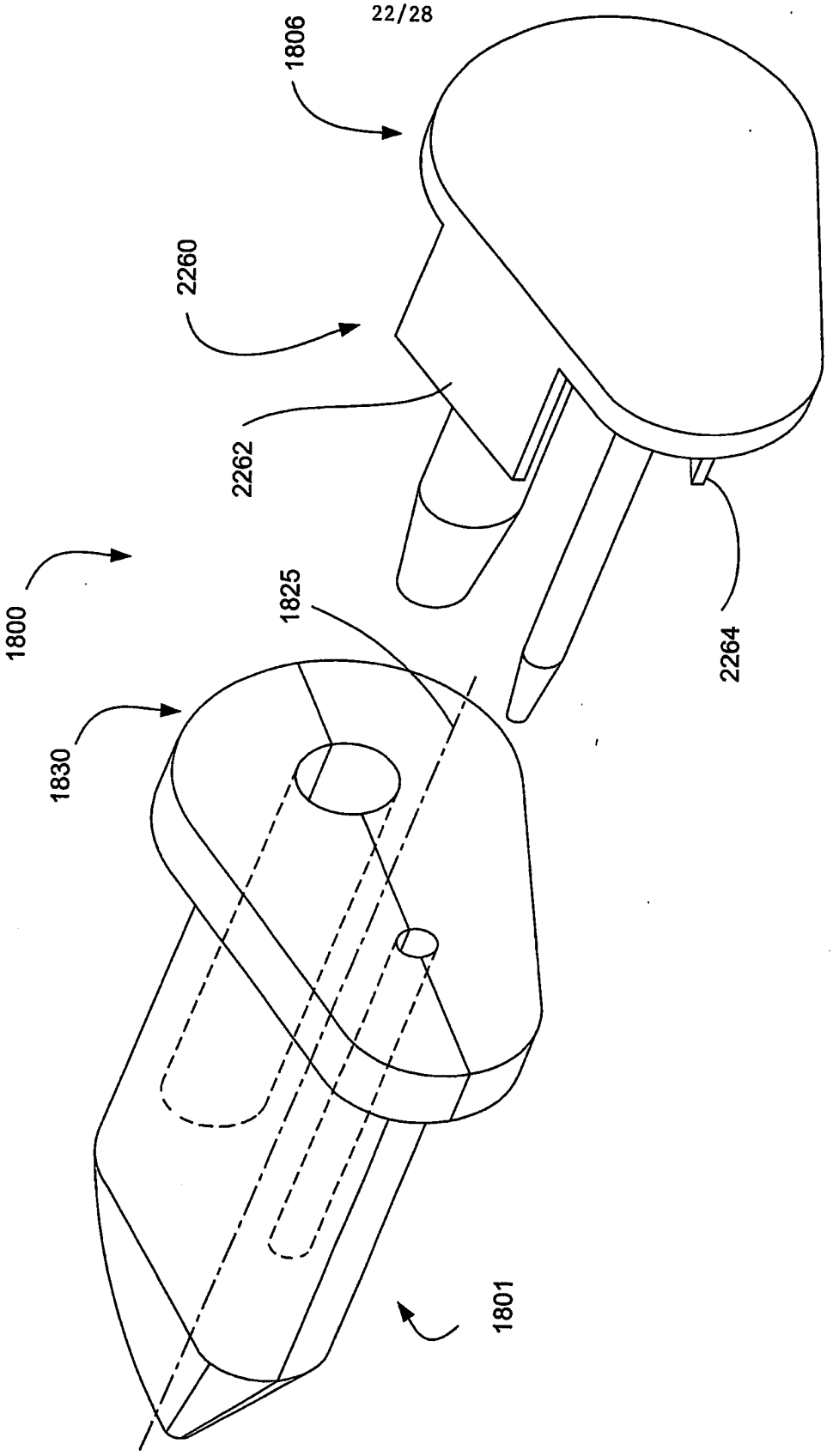


FIG. - 22A

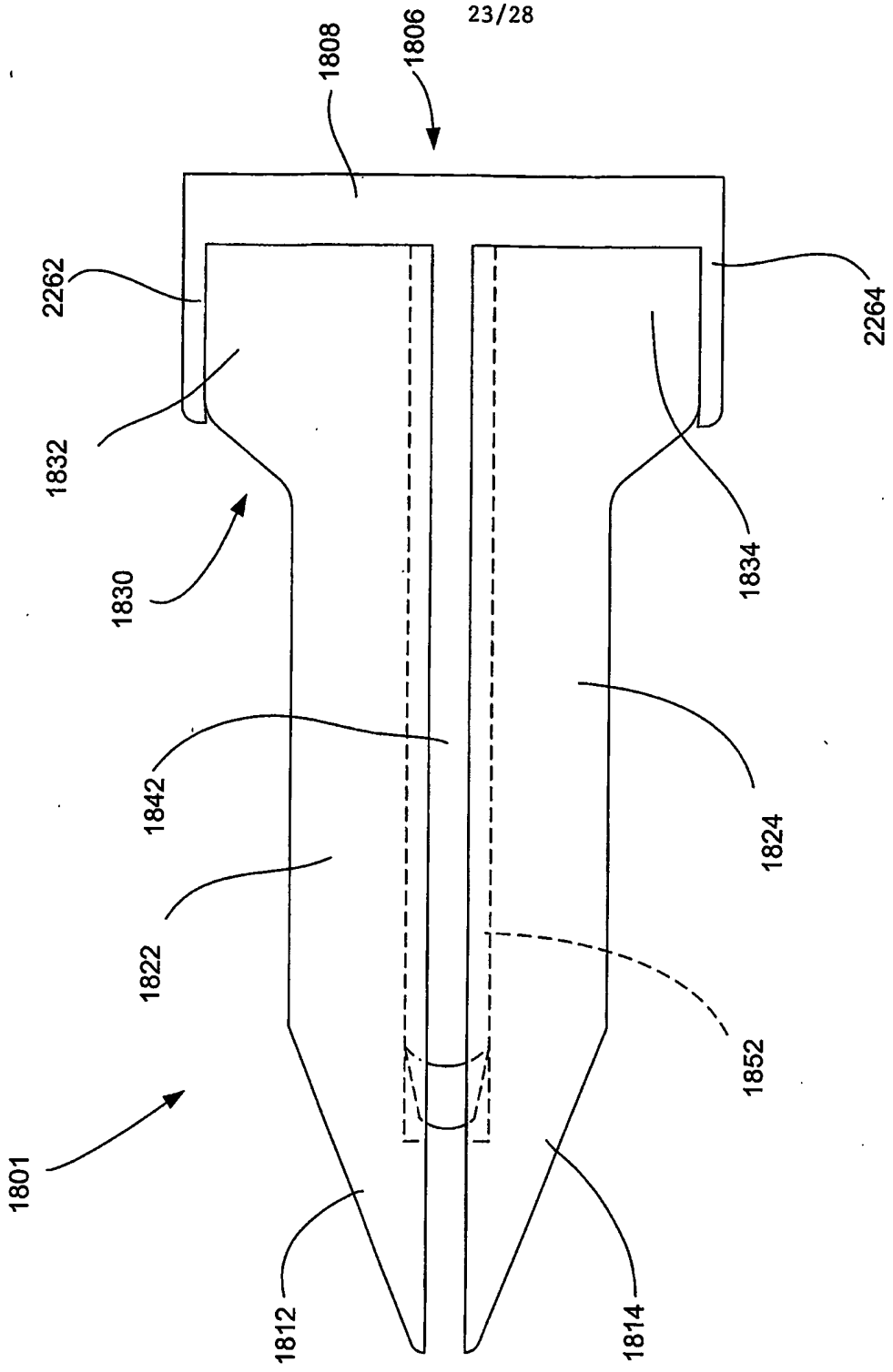
1808
1806
2262
2264
1832
1830
1834
1842
1824
1822
1852
1801
1812
1814

FIG. - 22B

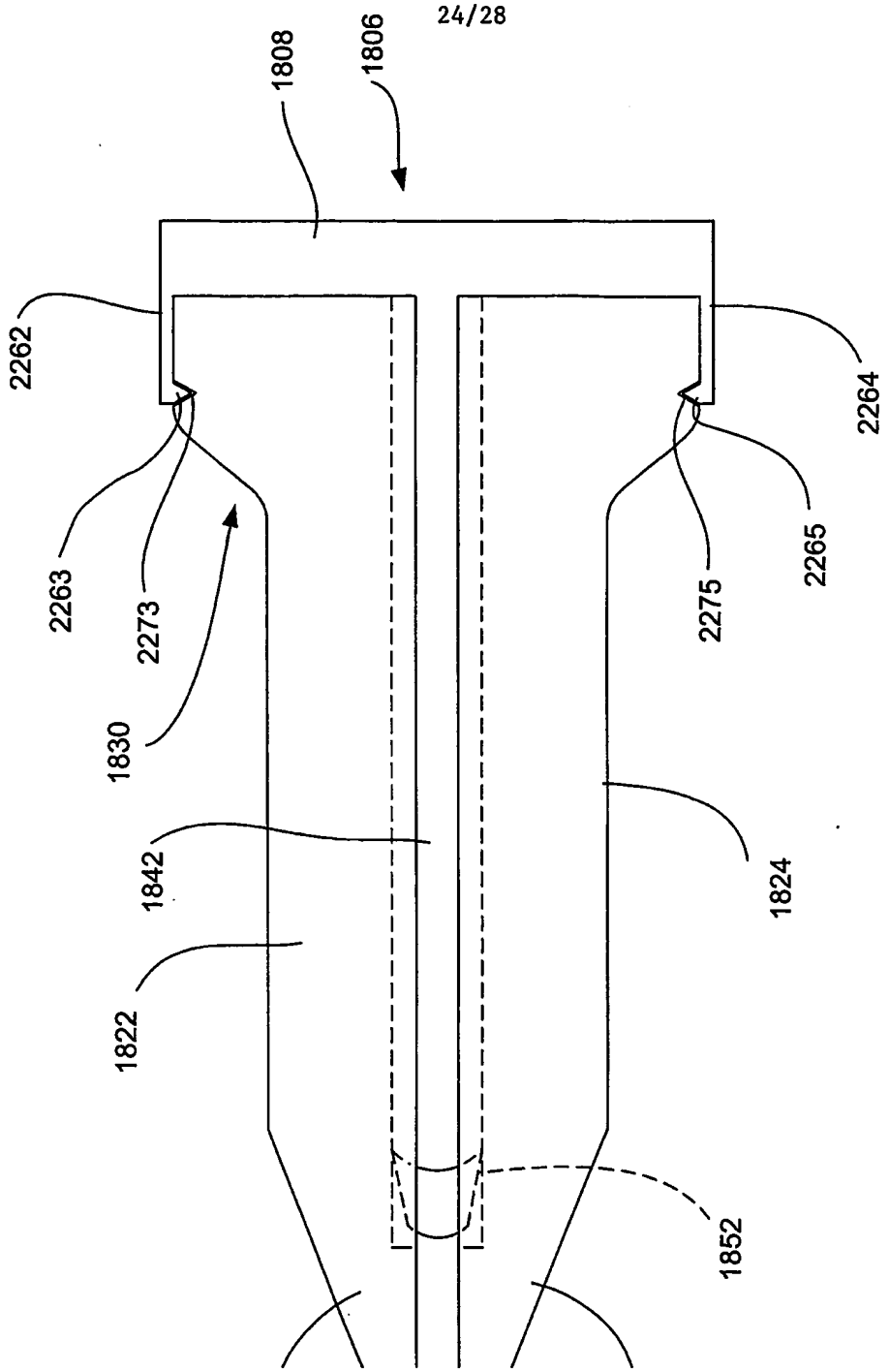
1808
1806
2262
2264
2263
2273
2275
2265
1830
1842
1824
1822
1852

FIG. 22C

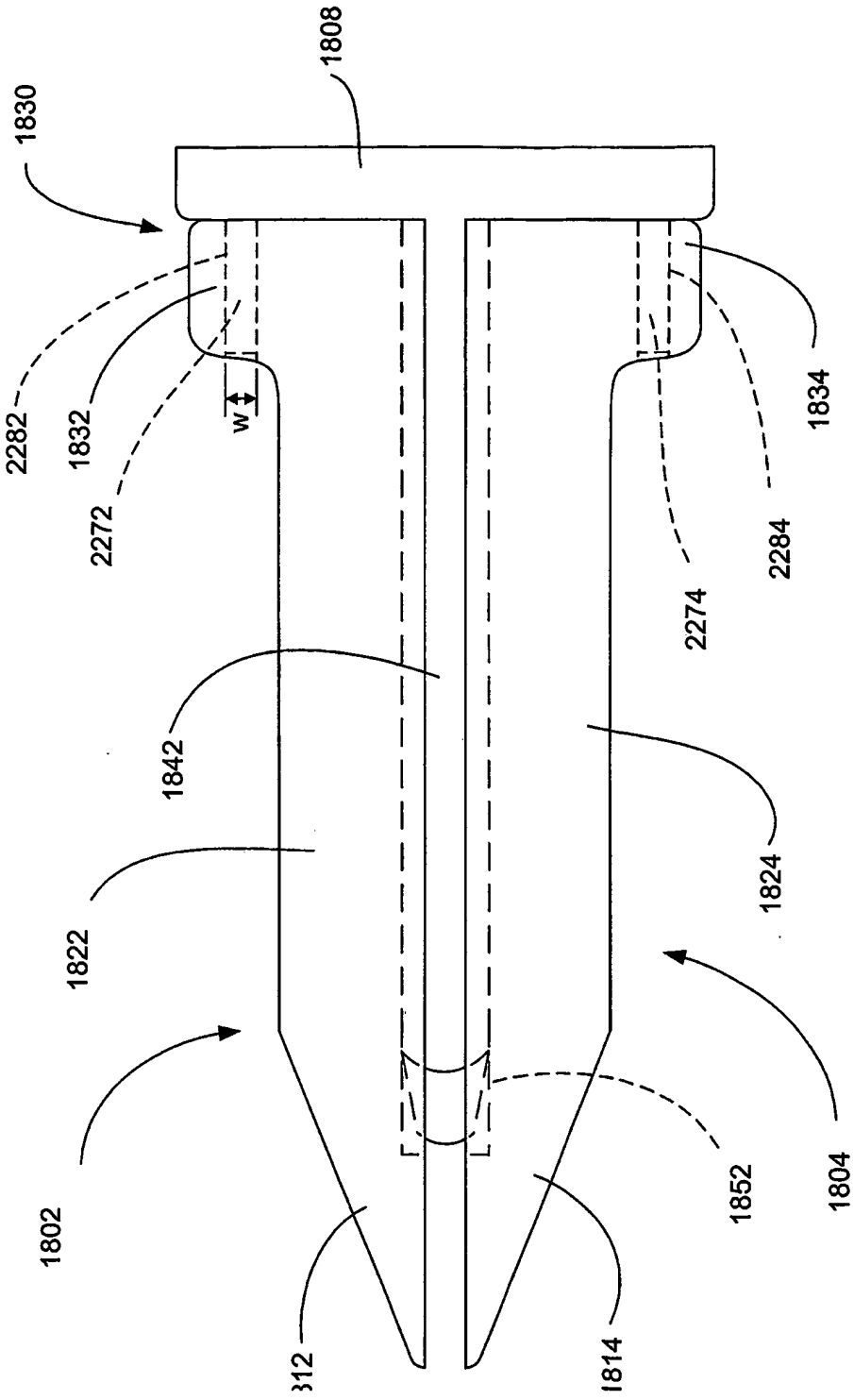
1808
1830
2282
1832
2272
W
1834
2284
2274
1842
1824
1822
1802
1852
1804
312
1814

FIG. - 22D

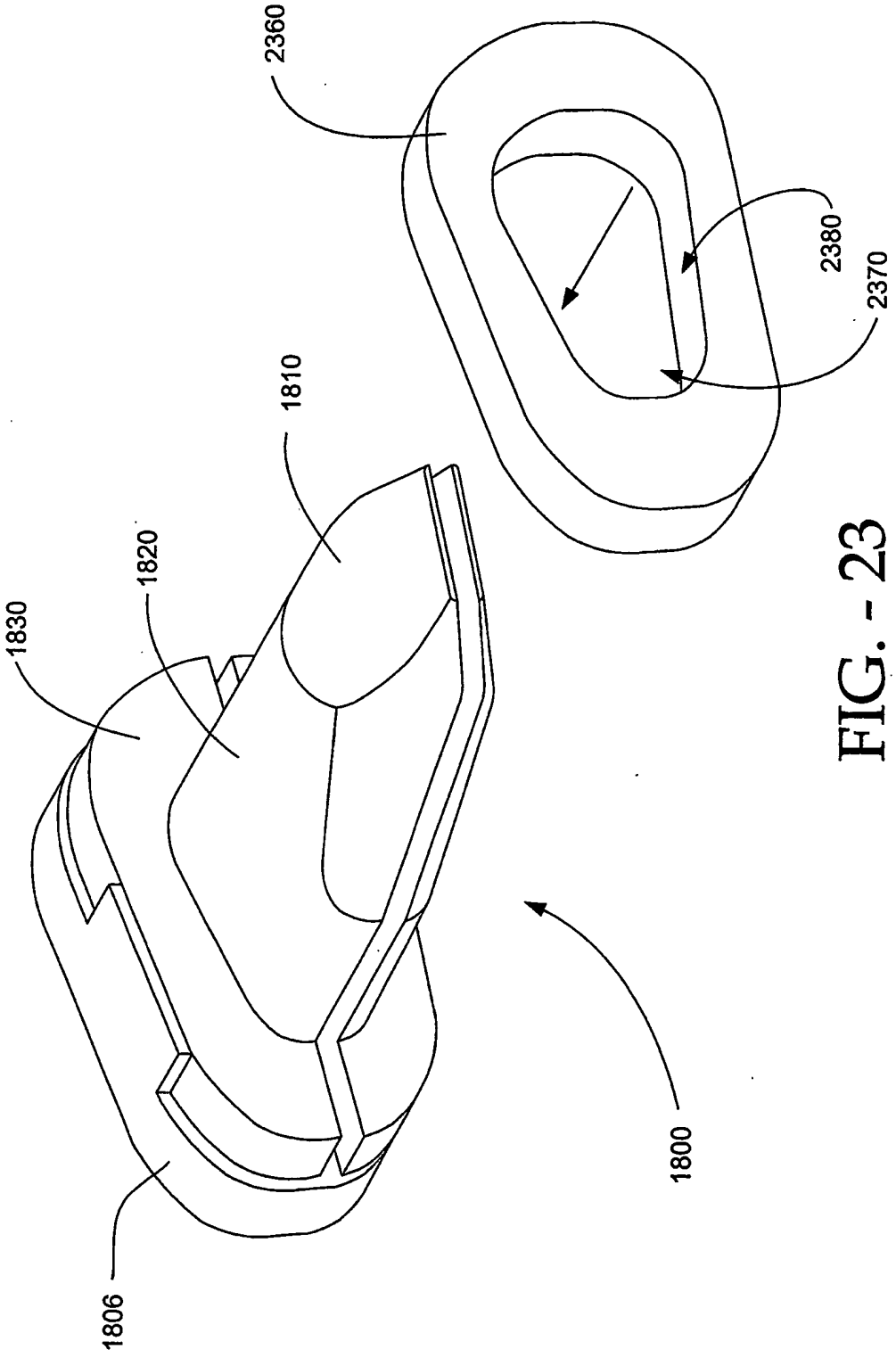


FIG. - 23

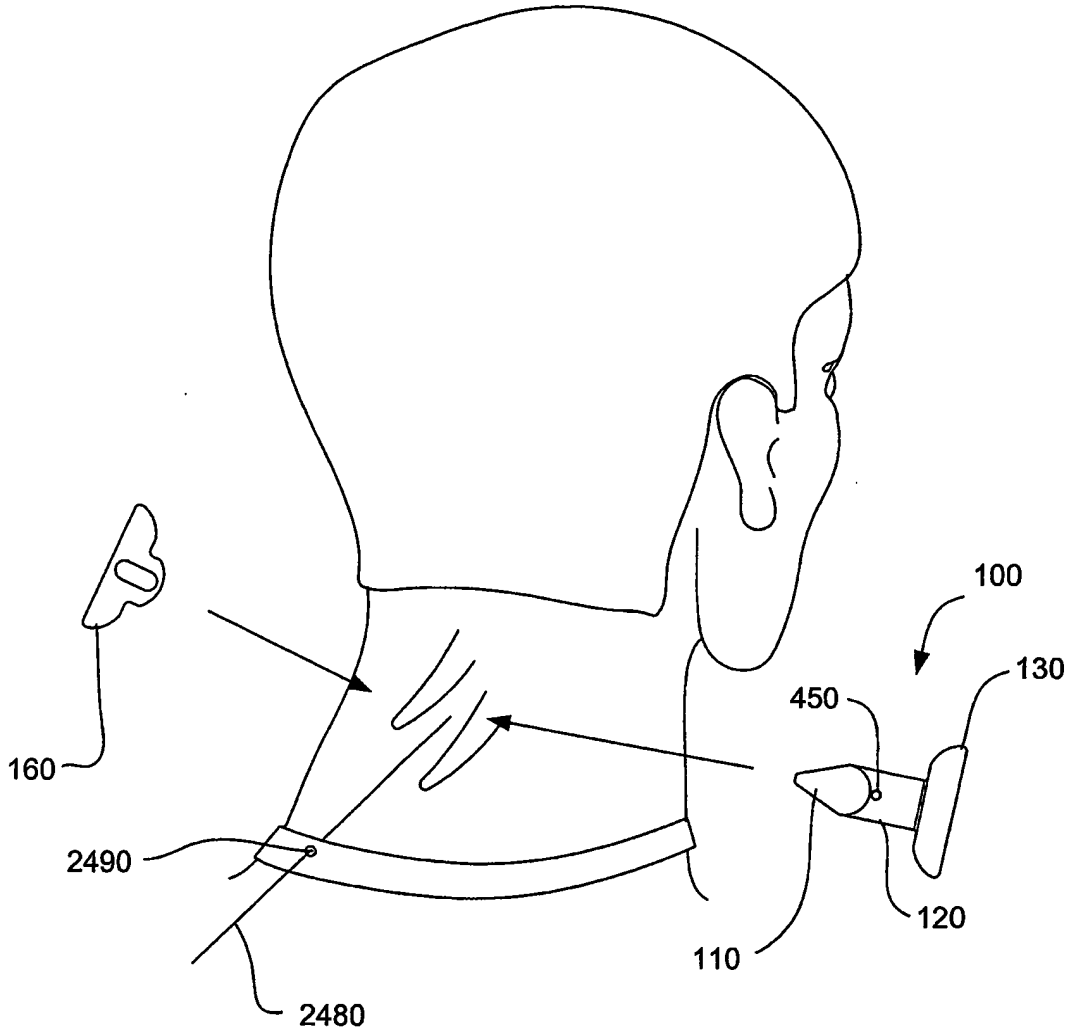


FIG. - 24

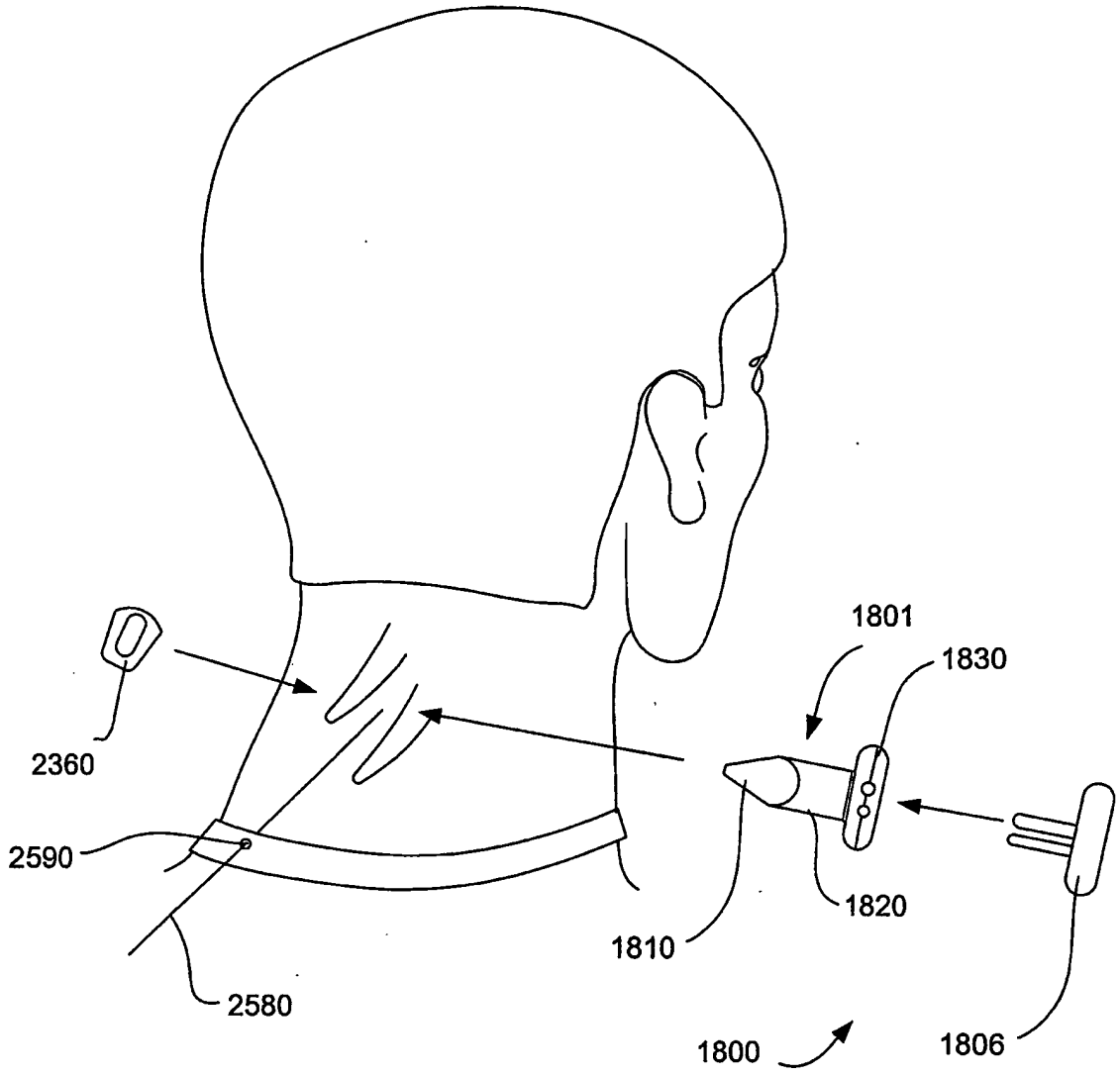


FIG. - 25